

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Freeline Therapeutics Holdings Limited¹

(Exact name of Registrant as specified in its charter)

England and Wales
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

Not Applicable
(I.R.S. Employer
Identification Number)

Stevenage Bioscience Catalyst
Gunnels Wood Road
Stevenage, Hertfordshire SG1 2FX
United Kingdom
+44 (0)1438 906870

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Freeline Therapeutics Inc.
c/o Corporation Service Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19808
(302) 636-5401

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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New York, NY 10017
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Boston, MA 02210
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards[†] provided pursuant to Section 7(a)(2)(B) of the Securities Act.

[†] The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

¹ We intend to alter the legal status of our company under English law from a private limited company by re-registering as a public limited company and changing our name from Freeline Therapeutics Holdings Limited to Freeline Therapeutics Holdings plc prior to the completion of this offering. See the section titled "Corporate Reorganization" in the prospectus which forms a part of this registration statement. The term Freeline Therapeutics Holdings plc in the prospectus which forms a part of this registration statement refers to Freeline Therapeutics Holdings Limited.

Explanatory Note

The sole purpose of this Amendment No. 2 to the Draft Registration Statement on Form F-1 of Freeline Therapeutics Holdings Limited (the “Company”) is to file exhibits 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9, 10.10, 10.11, 10.12 and 10.13. Accordingly, this Amendment No. 2 consists only of the facing page, this explanatory note, Part II, including the signature page and the exhibit index, and the exhibits filed herewith. This Amendment No. 2 does not contain a copy of the prospectus that was included in the Company’s Amendment No. 1 to the Company’s Draft Registration Statement on Form F-1 confidentially submitted to the U.S. Securities and Exchange Commission on June 12, 2020, and is not intended to amend or delete any part of the prospectus.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 6. Indemnification of Directors and Officers

Subject to the Companies Act 2006, members of the registrant's board of directors and its officers (excluding auditors) have the benefit of the following indemnification provisions in the registrant's articles of association:

Current and former members of the registrant's board of directors or officers shall be reimbursed for:

- (i) all costs, charges, losses, expenses and liabilities sustained or incurred in relation to his or her actual or purported execution of his or her duties in relation to the registrant, including any liability incurred in defending any criminal or civil proceedings; and
- (ii) expenses incurred or to be incurred in defending any criminal or civil proceedings, in an investigation by a regulatory authority or against a proposed action to be taken by a regulatory authority, or in connection with any application for relief under the statutes of the United Kingdom and any other statutes that concern and affect the registrant as a company, or collectively the Statutes, arising in relation to the registrant or an associated company, by virtue of the actual or purported execution of the duties of his or her office or the exercise of his or her powers.

In the case of current or former members of the registrant's board of directors, there shall be no entitlement to reimbursement as referred to above for (i) any liability incurred to the registrant or any associated company, (ii) the payment of a fine imposed in any criminal proceeding or a penalty imposed by a regulatory authority for non-compliance with any requirement of a regulatory nature, (iii) the defense of any criminal proceeding if the member of the registrant's board of directors is convicted, (iv) the defense of any civil proceeding brought by the registrant or an associated company in which judgment is given against the director, and (v) any application for relief under the Statutes in which the court refuses to grant relief to the director.

In addition, members of the registrant's board of directors and its officers who have received payment from the registrant under these indemnification provisions must repay the amount they received in accordance with the Statutes or in any other circumstances that the registrant may prescribe or where the registrant has reserved the right to require repayment.

The underwriting agreement the registrant will enter into in connection with the offering of ordinary shares being registered hereby provides that the underwriters will indemnify, under certain conditions, the registrant's board of directors and its officers against certain liabilities arising in connection with this offering.

Item 7. Recent Sales of Unregistered Securities

Issuances of Share Capital

The following list sets forth information regarding all unregistered securities sold by us or Freeline Therapeutics Limited since April 1, 2017, through the date of the prospectus that forms a part of this registration statement. In April 2020, Freeline Therapeutics Holdings Limited was incorporated in England and Wales with nominal assets and liabilities for the purpose of consummating a corporate reorganization by which it acquired the outstanding share capital of Freeline Therapeutics Limited. Following the share exchange by which the outstanding shares of Freeline Therapeutics Limited will be exchanged for the same number and class of newly issued ordinary shares of Freeline Therapeutics Holdings Limited, our ordinary shares will be redenominated as ordinary shares with a nominal value of £ per share. All share and per share information presented in this "Issuances of Share Capital" section do not reflect the -to- conversion that will occur as part of our corporate reorganization.

Set forth below is information regarding all securities issued by Freeline Therapeutics Limited without registration under the Securities Act since April 1, 2017.

On July 25, 2017, Freeline Therapeutics Limited issued 13,000,000 series A preferred shares to Syncona Portfolio Limited for aggregate consideration of £13,000,000.

On August 8, 2017, Freeline Therapeutics Limited issued 520,000 series A preferred shares to UTF General Partner LLP for aggregate consideration of £520,000.

On August 22, 2017, Freeline Therapeutics Limited issued 11,000,000 series A preferred shares to Syncona Portfolio Limited for aggregate consideration of £11,000,000.

On May 9, 2018, Freeline Therapeutics Limited issued 100,000 series A preferred shares to UTF General Partner LLP for aggregate consideration of £100,000.

On May 10, 2018, Freeline Therapeutics Limited issued 2,500,000 series A preferred shares to Syncona Portfolio Limited for aggregate consideration of £2,500,000.

On June 18, 2018, Freeline Therapeutics Limited issued:

- 20,000,000 series B preferred shares to Syncona Portfolio Limited for aggregate consideration of £30,000,000.
- 800,034 series B preferred shares to UTF General Partner LLP for aggregate consideration of £1,200,051.

On March 4, 2019, Freeline Therapeutics Limited issued:

- 20,000,000 series B preferred shares to Syncona Portfolio Limited for aggregate consideration of £30,000,000.
- 800,033 series B preferred shares to UTF General Partner LLP for aggregate consideration of £1,200,050.

On June 21, 2019, Freeline Therapeutics Limited issued:

- 16,666,667 series B preferred shares to Syncona Portfolio Limited for aggregate consideration of £25,000,000.
- 666,599 series B preferred shares to UTF General Partner LLP for aggregate consideration of £999,899.

On December 19, 2019, Freeline Therapeutics Limited issued 12,307,692 series C preferred shares to Syncona Portfolio Limited for aggregate consideration of \$39,999,999.

On March 12, 2020, Freeline Therapeutics Limited issued 721,120 A ordinary shares to Rentschler Biotechnologie Beteiligungs GmbH upon an exercise of 721,120 warrants at a strike price of £0.01 per share, resulting in aggregate proceeds of £7,211.20 to us.

On March 26, 2020, Freeline Therapeutics Limited issued;

- 230,249 series A preferred shares to Rentschler Biotechnologie Beteiligungs GmbH for aggregate consideration of £230,249.
- 448,631 series B preferred shares to Rentschler Biotechnologie Beteiligungs GmbH for aggregate consideration of £672,947.

Share Option Grants

Since April 1, 2017 through the date of the prospectus that forms a part of this registration statement, we and Freeline Therapeutics Limited have granted shares to employees, directors, consultants and service providers covering an aggregate of 12,047,440 ordinary shares with a nominal value of £0.00001 per share.

We believe that each of such issuances was exempt from registration under the Securities Act in reliance on (i) Section 4(a)(2) of the Securities Act or Rule 506 promulgated thereunder as transactions by an issuer not involving a public offering, (ii) under Rule 701 promulgated under the Securities Act in that transactions were under compensatory benefit plans and contracts relating to compensation or (iii) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was either an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act or was our employee, director or consultant and received the securities under our equity incentive plans. None of these transactions involved any underwriters, underwriting discounts or commissions or any public offering. All recipients had adequate access, through their relationships with us to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 8. Exhibits

(a) The following documents are filed as part of this registration statement:

- 1.1 Form of Underwriting Agreement.*
- 3.1 Form of Articles of Association of Freeline Therapeutics Holdings plc.*
- 4.1 Form of Deposit Agreement.*
- 4.2 Form of American Depositary Receipt (included in Exhibit 4.1).*
- 5.1 Form of opinion of Davis Polk & Wardwell London LLP.*
- 10.1 License Agreement, dated as of May 22, 2015, by and between Freeline Therapeutics Limited and UCL Business plc.#
- 10.2 Deed of Variation, dated as of January 24, 2017, to License Agreement, dated as of May 22, 2015, by and between Freeline Therapeutics Limited and UCL Business plc.#
- 10.3 Second Deed of Amendment, dated as of May 24, 2018, to the License Agreement, dated as of May 22, 2015, by and between Freeline Therapeutics Limited and UCL Business plc.#
- 10.4 Third Deed of Amendment and Termination, dated as of December 18, 2019, by and between Freeline Therapeutics Limited and UCL Business Ltd.#
- 10.5 Collaboration Agreement, dated as of April 10, 2018, by and between Freeline Therapeutics Limited and Cell Therapy Catapult Limited.#
- 10.6 Service Agreement, dated as of May 14, 2018, by and between Freeline Therapeutics Limited and Aldevron, LLC.#
- 10.7 Biopharma Services Agreement, dated as of June 5, 2016, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group).#
- 10.8 Services Agreement, dated as of October 11, 2016, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group).#
- 10.9 Amendment No. 2, dated as of September 7, 2018, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group), to Services Agreement, dated as of October 11, 2016.#

- 10.10 Amendment No. 3, dated as of April 9, 2020, by and between Freeline Therapeutics Limited and Henogen SA (a subsidiary of the NOVASEP Group), to Services Agreement, dated as of October 11, 2016.#
- 10.11 Development and Manufacturing Services Agreement, dated as of October 6, 2017, by and between Freeline Therapeutics Limited and Brammer Bio MA, LLC.#
- 10.12 License Agreement, dated as of March 24, 2017, by and between Freeline Therapeutics Limited and St. Jude Children’s Research Hospital.#
- 10.13 Amendment, dated as of February 28, 2020, to License Agreement, dated as of March 25, 2017, by and between Freeline Therapeutics Limited and St. Jude Children’s Research Hospital.#
- 10.14 Form of Freeline Therapeutics Holdings plc 2020 Share Option Scheme.*+
- 10.15 Form of Deed of Indemnity between the registrant and each of its members of senior management and directors.*
- 21.1 List of subsidiaries.*
- 23.1 Consent of Deloitte LLP.*
- 23.2 Consent of Davis Polk & Wardwell London LLP (included in Exhibit 5.1).*
- 24.1 Powers of attorney (included on signature page to the registration statement).*

* To be filed by amendment.

+ Indicates management contract or compensatory plan.

Portions of this exhibit (indicated by asterisks) have been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the registrant if disclosed.

(b) Financial Statement Schedules

None.

Item 9. Undertakings

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York on _____, 2020.

Freeline Therapeutics Holdings Limited

By: _____

Name: Theresa Heggie
Title: Chief Executive Officer

By: _____

Name: Brian Silver
Title: Chief Financial Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Theresa Heggie and Brian Silver and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on , 2020 in the capacities indicated:

<u>Name</u>	<u>Title</u>
_____ Theresa Heggie	Chief Executive Officer (principal executive officer)
_____ Brian Silver	Chief Financial Officer (principal financial officer and principal accounting officer)
_____ Chris Hollowood, Ph.D.	Chairman of the Board of Directors
_____ Amit Nathwani, M.D.	Director
_____ Julia P. Gregory	Director
_____ Jeffrey Chodakewitz, M.D.	Director
_____ Martin Andrews	Director

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Freeline Therapeutics Holdings Limited has signed this registration statement on _____, 2020.

FREELINE THERAPEUTICS, INC.

By: _____

Name: Brian Silver

Title: Chief Financial Officer

LICENCE AGREEMENT

- (1) FREELINE THERAPEUTICS LIMITED
- (2) UCL BUSINESS PLC

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Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

THIS AGREEMENT is made as of 22 May 2015 (the “**Effective Date**”)

BY AND BETWEEN:

- (1) **FREELINE THERAPEUTICS LIMITED**, a company duly organised and validly existing under the laws of England (company number 9500073) with its registered office at 90 High Holborn, London, WC1V 6XX (“**Liverco**”); and
- (2) **UCL BUSINESS PLC**, a public company duly organised and validly existing under the laws of England (company number 02776963) with its registered office at The Network Building, 97 Tottenham Court Road, London, W1T 4TP (“**UCLB**”).

WHEREAS:

- (A) Liverco is a newly incorporated company that has been established for the purposes of exploiting certain of the Technology (as defined hereunder), with a primary (but not exclusive) focus on the field of gene therapy to target liver cells, or treat or diagnose conditions affecting the liver, or affected by conditions of the liver;
- (B) UCLB is a public company established by UCL to assist in the commercialisation of technology arising from UCL’s faculties and is responsible for technology development and commercialisation transactions for UCL;
- (C) Professor Amit Nathwani is a leading academic and expert in the development of liver directed AAV gene therapy and is an employee and academic at UCL and leads and supervises the AN Laboratory (as defined below);
- (D) Through his own research and the research undertaken at the AN Laboratory, certain inventions, discoveries and know-how have been developed concerning liver directed AAV gene therapy in a number of therapeutic indications;
- (E) Pursuant to his employment conditions, and the conditions of employment or studentship existing amongst those who work or collaborate in the AN Laboratory and UCL’s governance, all Intellectual Property generated by AN or by, at or within the AN Laboratory (irrespective of the individual or their status within the AN Laboratory) are initially owned by UCL, and UCLB has the automatic exclusive right to assign and/or license all such Intellectual Property by virtue of its arrangements with UCL;
- (F) AN has, and the individuals working within the AN Laboratory have, assigned all their respective rights to the Technology to be licensed and/or assigned hereunder to UCLB;
- (G) Liverco was granted a licence to the Original Programs with effect from the Effective Date and now with effect from the Amendment Date licences in respect of the Additional Programs are to be added to this Agreement; and,
- (H) Recognising that certain research Programs are currently ongoing within the AN Laboratory, Liverco now wishes to take a licence to certain of the Technology existing as

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of the Effective Date, and obtain an option to acquire other parts of the Technology which is existing as of the Effective Date and which will arise after the Effective Date through the ongoing performance of certain Programs, in each case upon the terms of this Agreement, and UCLB wishes to grant such rights to Liverco and does so with the consent and support of UCL and AN.

NOW, THEREFORE, the Parties, in consideration of the mutual covenants and undertakings herein and for other good and valuable consideration, intending to be legally bound, **HEREBY AGREE** as follows;

1 DEFINITIONS AND INTERPRETATION

1.1 In this Agreement, each of the capitalised words and expressions set out below shall have the meanings set forth against that capitalised word or expression, unless expressly provided otherwise;

“**AAV**” means an adeno-associated virus;

“**Academic Information**” has the meaning set out in Clause 4.3;

“**Academic Collaborator(s)**” means any Academic Organisation which is actively collaborating with UCL on Academic Research permitted pursuant to Clause 4;

“**Academic Organisation**” means an organisation (excluding any organisation that is established in the People’s Republic of China, or that is directly or indirectly under the control or direction of any such organisation) engaged in the conduct of academic research or the non-commercial funding of academic research, comprising academic institutions, charities, non-for-profit organisations and government bodies including the national health service and equivalent organisations anywhere in the world;

“**Academic Research**” means academic research which is undertaken by UCL alone or in collaboration with another Academic Organisation, excluding any Commercial Research;

“**Academic Reports**” has the meaning set out in Clause 4.3.2;

“**Academic Rights**” has the meaning set out in Clause 4.1;

“**Additional Patent Right**” means the [**] Patents and “**Additional Patent Rights**” means both of the foregoing;

“**Additional Program**” means the [**] Program, and “**Additional Programs**” means both of the foregoing;

“**Additional Program IP**” means the [**] Program IP, or as the context requires both of the foregoing;

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

“Additional Program Licence” means the [**], and **“Additional Program Licences”** means both of the foregoing;

“Additional Royalty Product” means a [**], and **“Additional Products”** means both of the foregoing;

“Affiliate” means any entity that directly or indirectly controls, is controlled by, or is under common control with a Party, for so long as such control exists. For the purposes of this definition of Affiliate, “control” and “controlled” means either (a) with respect to any person or entity, ownership directly or indirectly of more than fifty (50%) per cent of the shares of stock entitled to vote for the election of directors, in the case of a company or corporation, or more than fifty (50%) per cent of equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a person controls or has the right to control the board of directors or equivalent governing body of the relevant entity, or the ability generally to cause the direction of the management or policies of an entity. In the case of certain entities organised under the laws of certain countries, where the maximum percentage ownership permitted by law for a foreign investor is less than fifty (50%) per cent, in such case such lower percentage shall be substituted in the preceding sentence provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement UCL shall be deemed an Affiliate of UCLB and vice versa; and (ii) Liverco’s Affiliates shall be limited to its subsidiaries (as defined in section 1159 of the Companies Act 2006) from time to time;

“Agreement” means this agreement together with its schedules, each as may be amended from time to time in accordance with the terms of this Agreement;

Amendment Date means 23 January 2017;

“AN” or “Professor Amit Nathwani” means Prof. Amit Nathwani [**];

“AN Laboratory” means from time to time prior to, on and/or following the Effective Date, those members of the research group(s) at UCL led by AN, who at the relevant time were or are under the supervision or direction of AN (i) prior to the Effective Date (excluding Professor [**] (ii) on or after the Effective Date and were undertaking any activities funded in whole or part by any grant under which AN is named as an applicant and whilst AN is employed by, consults for or otherwise holds any position at or undertakes or supervises any research at UCL or UCLB (but excluding any individuals from the date Liverco has confirmed, in writing to UCLB, that they are deemed outside of the AN Laboratory in accordance with the provisions of Clause 6.7, until such time as Liverco revokes such confirmation in accordance with the provisions of Clause 6.8 whereupon such individuals will not be excluded with effect from the date of that notice). [**] definition does not include the individuals in the definition of the Haemostasis Group unless the work of such individuals is in relation to isolating, characterising and/or developing a therapy or therapeutic product;

“**Assignment**” has the meaning set out in Clause 8.2;

“**Background Licence**” has the meaning set out in Clause 2.1;

“**Background Materials**” means (i) those materials listed in Part B Schedule 3; and (ii) any materials Controlled by UCLB (free from any restriction or encumbrance) which are not Program Materials or the [**] (as such term is defined in the [**]) and which have been used by AN and/or the AN Laboratory in connection with any of the (a) Programs (other than the Second Serotype Program) prior to and/or as of the Effective Date; and/or (b) the Second Serotype Program before, on or after the Effective Date; and/or (c) the Additional Programs before and/or as of, the Amendment Date;

“**Best Endeavours**” means the use by UCLB of best endeavours provided that the foregoing shall not oblige UCLB to pay monies or incur external costs or expenses, but shall require internal management effort and activity to be deployed by UCLB management and AN using UCLB’s best efforts and where requested by Liverco, UCLB’s management and/or AN shall travel and attend meetings to procure the objective, with any reasonable third party travel and subsistence costs being met by Liverco;

[**];

“**[**] Licence**” has the meaning set out in Clause 2.4.9;

“**[**] Patent Rights**” means the patent application to be filed by UCLB claiming the inventions derived from the [**] Program including any described in Part F of Schedule 2 under the title [**] Program Know How and/or [**] Materials, and all Patent Rights derived therefrom;

“**[**] Product**” means any AAV-directed gene therapy product that is not an Original Product and (i) [**] that [**] set out [**], and/or (ii) which would infringe any of the [**] but for the licence granted to Liverco hereunder;

“**[**] Program**” means the program of research defined in Schedule 1 under the title [**] Program as conducted prior to the Amendment Date;

“**[**] Program IP**” means (i) the [**] Patent Rights and (ii) excluding Manufacturing Know-How, all Know-How described in Part F of Schedule 2 under the title [**] Program Know How; and (iii) the materials listed in Part F of Schedule 2 under the title [**] Materials (together with all IP in the same);

“**Buy-Out Option**” has the meaning set out in Clause 14.1;

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

“CDA” means the confidentiality agreement executed between UCLB and [**] dated [**];

“Collaborative Research Project” has the meaning set out in Clause 4.5;

“Combination Product” has the meaning set out in paragraph 4 of Part A Schedule 8;

“Commercial Licence” has the meaning set out in Clause 3.3;

“Commercial Research” means any research (i) that is, in whole or part, funded by a person or entity that is not a Funder; or (ii) that is undertaken at the request of or for the benefit of any entity that is not an Academic Organisation involved in such research; or (iii) that is undertaken (as opposed to funded) in collaboration with any entity which is not an Academic Organisation; or (iv) under which a Third Party, which is not an Academic Organisation participating in such research, will acquire any rights in (including by way of assignment or licence) or control over the results of such research;

“Competitive Product” means any product or therapy that is competitive to or equivalent (whether structurally, functionally or through mechanism of action) to any Royalty Product, including any product or therapy that may be considered a generic, biosimilar and/or a “me-too” product or therapy or otherwise infringes any of the Licensed Patents or makes use of any of the Technology or infringes any of the Patent Rights that are the subject of the HLP Promoter Licence;

“Competing Entrant” has the meaning set out in Clause 12.11;

“Confidential Information” has the meaning set out in Clause 17.1;

“Control” or “Controlled” means in respect of a Party, that Intellectual Property (or those materials) which such Party (which in the case of UCLB means UCLB or UCL) (i) owns and is able, without breaching any obligation owed by it or (by rule of law) having to obtain the consent of any co-owner, to license (or in the case of materials supply) the same to a third party (including a Party to this Agreement) for the applicable Product or use; or (ii) is licensed to use (other than by the other Party to this Agreement) and is entitled under the terms of the licence to which they are a party to sub-license (or in the case of materials supply) the same to a third party (including a Party to this Agreement) for the applicable Product or use without having to obtain consent from such third party;

“Core Countries” means [**] and “Core Country” means any one of them;

“Cover”, “Covering” or “Covered” means in the case of a product, that such product (i) would, were it not for the applicable licence granted and subsisting hereunder, infringe the applicable Patent Rights so licensed hereunder; (ii) has been manufactured for commercial supply using the applicable Intellectual Property licensed to Liverco hereunder, which use, were it not for the applicable licence granted and subsisting

hereunder, would otherwise constitute an infringement or actionable misuse of such Intellectual Property; or (iii) has been manufactured for commercial supply using any of the applicable Program Materials provided to Liverco hereunder;

“**Defaulting Party**” has the meaning set out in Clause 21.4;

“**Disclosing Party**” has the meaning set out in Clause 17.1;

“**Disclosure Notification**” has the meaning in Clause 5.2;

“**Enforcement Action**” has the meaning set out in Clause 16.2;

“**Excluded Field**” means any liver targeted gene therapy using an AAV vector (i) for [**] or, (ii) [**] or, (iii) [**];

“**Exclusive Field**” means the FIX Field, the [**], the Fabry Field and the [**] Field;

“**Existing Licences**” has the meaning set out in Clause 4.7;

“**Exploit**” and “**Exploiting**” means to make, have made, import, export, use, sell or offer for sale, including to research, experiment, develop, commercialise, file for, obtain and maintain Regulatory Approvals, manufacture, to have manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of, and “**Exploitation**” shall mean the act of Exploiting;

“**European Union**” means those countries comprising the member states within any of the European Union, the European Economic Area and/or the European Free Trade Association, in each case as existing as of the Effective Date, together with any accession countries to any of the foregoing from time to time;

“**Fabry Field**” means the treatment, prevention, cure, management, diagnosis and/or control of conditions concerning or related to alpha galactosidase A enzyme, including the condition referred to as ‘Fabry Disease’, and associated symptoms;

“**Fabry Licence**” has the meaning set out in Clause 2.4.1;

“**Fabry Patent Rights**” means (i) those patent applications listed in Part A of Schedule 2 under the title ‘Fabry Patents’ and all Patent Rights derived therefrom; and, (ii) any Future Patents filed in respect of any of the Program Know-How identified in (ii) of the definition of Fabry Program IP;

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“Fabry Product” means, excluding Additional Royalty Products, any AAV-directed gene therapy product which is indicated (by way of its product label or package insert) for use in the Fabry Field and is Covered by any of the Fabry Program IP, Manufacturing Know-How, Serotype IP and/or Promoter Program IP licensed to Liverco hereunder;

“Fabry Program” means the program of research defined in Schedule 1 under the title Fabry Program as conducted prior to the Effective Date;

“Fabry Program IP” means the (i) Fabry Patent Rights and (ii) Program Know-How applicable to Exploitation within the Fabry Field;

“Field” means all uses and applications without restriction;

“Final Written Report” means the final written report approved by AN and written following completion of the Second Serotype Program in accordance with the applicable project plan outlined in Schedule 1, and which shall provide a complete report of the results, findings and activities arising from the Second Serotype Program;

“First Commercial Sale” means the first arm’s length commercial sale of the applicable Royalty Product in a country by Liverco or by a Sub-Licensee pursuant to a sub-license granted hereunder, in each case following the grant of a Marketing Approval for the applicable Royalty Product in such country;

“First Serotype Licence” has the meaning set out in Clause 2.4.6

“First Serotype Patent Rights” means (i) those patent applications listed in Part A of Schedule 2 under the title ‘First Serotype Patents’ and all Patent Rights derived therefrom; and (ii) any Future Patents filed in respect of any of the Program Know-How identified in (ii) of the definition of First Serotype Program IP;

“First Serotype Program” means the program of research defined in Schedule 1 under the title First Serotype Program as conducted prior to the Effective Date;

“First Serotype Program IP” means (i) the First Serotype Patent Rights; and (ii) Program Know-How existing at the Effective Date applicable to the serotypes isolated, and/or designed and/or made under the First Serotype Program or Covered by any of the First Serotype Patent Rights, and their Exploitation;

[**] means, excluding Additional Royalty Products, any gene therapy product containing or incorporating the [**] any sequence variant or derivative of that gene, for the amelioration, prevention or treatment [**];

“FIX Field” means the treatment, prevention, cure, management, diagnosis and/or control of conditions concerning or related to Factor IX, including the condition referred to as ‘Haemophilia B’, and associated symptoms;

“FIX Licence” has the meaning set out in Clause 2.4.2;

“FIX Patent Rights” means (i) those patent applications listed in Part A of Schedule 2 under the title ‘FIX Patents’ and all Patent Rights derived therefrom; and (ii) any Future Patents filed in respect of any of the Program Know-How identified in (ii) of the definition of FIX Program IP, and (iii) the [**] Patent Rights;

“FIX Product” means, excluding Additional Royalty Products, any AAV-directed gene therapy product which is indicated (by way of its product label or package insert) for use in the FIX Field and is Covered by any of the FIX Program IP, [**] Program IP, Manufacturing Know-How, Serotype IP and/or Promoter Program IP licensed to Liverco hereunder;

“FIX Program” means the program of research defined in Schedule 1 under the title FIX Program as conducted prior to the Effective Date;

“FIX Program IP” means the (i) FIX Patent Rights and (ii) Program Know-How applicable to Exploitation within the FIX Field;

“[] Field”** means the treatment, prevention, cure, management, diagnosis and/or control of conditions concerning or related to [**], including the condition the condition referred to as ‘[**]’, and associated symptoms;

“[] Licence”** has the meaning set out in Clause 2.4.3;

“[] Patent Rights”** means (i) those patent applications listed in Part A of Schedule 2 under the title ‘[**]’ and all Patent Rights derived therefrom; and (ii) any Future Patents filed in respect of any of the Program Know-How identified in (ii) of the definition of [**];

“[] Product”** means, excluding Additional Royalty Products, any AAV-directed gene therapy product which is indicated for use (by way of its product label or package insert) in the [**] and is Covered by any of the [**], Manufacturing Know-How, Serotype IP and/or Promoter Program IP licensed to Liverco hereunder;

“[] Program”** means the program of research defined in Schedule 1 under the title [**] as conducted prior to the Effective Date;

“[] Program IP”** means the (i) [**] Patent Rights and (ii) Program Know-How applicable to Exploitation within the [**] Field;

“FX Vector” means (i) a vector that [**], or (ii) a vector that [**] that [**];

“FX Vector IP” means any Intellectual Property Rights existing or arising in [**] including any Patent Rights filed in respect of the same by or on behalf of UCLB from time to time;

“FX Vector Product” means any AAV-directed gene therapy that is not a Royalty Product and which incorporates within it the FX Vector other than where the vector includes [**];

“Funder” means an academic, charitable or other not-for-profit organisation (excluding any that is established in the [**] or that is directly or indirectly under the control or direction of any such organisation) including academic institutions, charities, and government bodies;

“Future Patents” means, excluding the Additional Program Patents, any Patent Rights filed by or on behalf of UCLB from time to time that claim any of the applicable Program Know-How;

“[] Field”** means the treatment, prevention, cure, management, diagnosis and/or control of conditions concerning or related to [**], including the condition referred to as ‘[**]’, and associated symptoms;

“[] Licence”** has the meaning set out in Clause 2.4.4;

“[] Patent Rights”** means any Patent Rights filed by or on behalf of UCLB from time to time in respect of (i) the constructs identified under the [**] Program including those identified in Part D of Schedule 2; and (ii) any Future Patents filed in respect of any of the Program Know-How identified in (ii) of [**] Program IP;

“[] Product”** means, excluding Additional Royalty Products, any AAV-directed gene therapy product which is indicated (by way of its product label or package insert) for use in the [**] Field and is Covered by any of the [**] Program IP, Manufacturing Know-How, Serotype IP and/or Promoter Program IP licensed to Liverco hereunder;

“[] Program”** means the program of research defined in Schedule 1 under the title “[**] Program”;

“[] Program IP”** means (i) [**] Patent Rights; and (ii) Program Know-How applicable to Exploitation within the [**] Field;

“[] Licence”** has the meaning set out in Clause 2.4.8;

“[] Patent Rights”** means any Patent Rights filed by or on behalf of UCLB from time to time in respect of (i) any work undertaken by AN and/or the AN Laboratory prior to, on or after the Effective Date under or pursuant to the [**] Program as set out in Schedule 1, but excluding the [**]; and (ii) any Program Know-How identified in (ii) of [**] IP;

“**[**] Program**” means the program of research carried out prior to the Effective Date relating to the gain of function over the [**] and defined in Schedule 1 under the title [**];

“**[**] Program IP**” means (i) the [**] Patent Rights; and, (ii) the Program Know-How applicable to Exploitation within the [**];

“**Haemostasis Group**” means those individuals that are [**];

“**HLP1 Promoter Sequence**” means the gene transcription promoter having the sequence set out in Part C of Schedule 2 under the title “HLP1 Promoter Sequence”;

“**HLP2**” means the gene transcription promoter having the sequence set out in Part C of Schedule 2 under the title “HLP2 Promoter Sequence”;

“**HLP Promoter Licence**” the licence executed between the Parties [**] in relation to, *inter alia*, the Patent Rights owned by UCLB [**] with respect to the HLP1 Promoter Sequence dated [**] as may be amended from time to time;

“**HLP Royalty**” the royalty paid or payable by Liverco pursuant to the HLP Promoter Licence;

“**Improvement**” means any improvement, enhancement, development or advancement (together with all Intellectual Property in the same) created, generated or developed by AN (in the course of his activities or role at or for UCL or UCLB) and/or the AN Laboratory, over any of (i) the Products; (ii) the Program IP; and/or (iii) Program Materials which, in each case if used, deployed or incorporated in the Exploitation of any product, therapy, process or service would (a) result in such product, therapy, process or service falling within the scope of, or otherwise infringing any one or more claims of any of the Licensed Patents, or using any of the Program Know-How, Program Materials, Serotype IP and/or Promoter Program IP; or (b) still constitute a Product;

“**Improvement Negotiation Period**” means in respect of each Improvement or New Invention (as applicable), the period commencing with the date the applicable Disclosure Notificatic complying with Clause 5.2.2) is deemed to have been received by Liverco and expiring [**] after the date such Disclosure Notification is deemed to have been so received;

“**Improvement Period**” has the meaning set out in Clause 5.1;

“**Indemnity Claim**” has the meaning set out in Clause 20.1;

“Indemnified Party” has the meaning set out in Clause 20.1;

“Insolvency Event” means the occurrence of any of the following events or circumstances (or any analogous event or circumstance in a jurisdiction other than England and Wales) in relation to the relevant entity: (i) being deemed unable to pay its debts as defined in section 123 Insolvency Act 1986, (ii) entering into a voluntary arrangement or any other composition, scheme or arrangement with (or assignment for the benefit of) its creditors; (iii) the appointment of a receiver, administrator or insolvency manager over the whole or the majority of its business or assets, and which appointment is not appealed or set aside within [**]; (iv) an order is made or a resolution is passed for its winding up (except for the purposes of a bona fide solvent reorganisation); (v) an order for bankruptcy or dissolution or the making of an administration order is made which is not appealed or set aside within [**] of it being made; or (vi) ceasing to carry on business for any continuous period in excess of [**] claiming the benefit of any statutory moratorium;

“Intellectual Property” or “IPR” or “IP” means all Patent Rights, claims in or rights to Patent Rights, rights in designs (including design patents, registered designs and unregistered designs), copyright, rights in software, database rights, rights in data, inventions, rights in Know-How, trade secrets and confidential information, and any and all other similar or equivalent rights to any of the foregoing situated in any country in the world, in each case for their full term and any extensions, together with applications for any of the foregoing, the right to apply for any of the foregoing in any part of the world and the right to claim priority in respect of any of the foregoing;

“Know-How” means all technical and other information, knowledge, ideas, concepts, discoveries, data, designs, know-how, trade secrets, inventions (which at the relevant time are not the subject of a Patent Right), formulae, methods, software sequences, models, procedures, designs for experiments, trials and tests and results of the same, testing methods, processes, specifications and techniques, clinical data and manufacturing data;

“Know-How Period” has the meaning set out in Clause 12.7;

“Laboratory Notebooks” means all laboratory notebooks in UCL’s possession, custody or control which emanate from laboratories at UCL, in so far as they concern or contain information relating to any of the Programs, Program IP, Materials or UCL Background IP;

“Licence” means one of the Original Licences, Additional Program Licences or [**] Vector Licence and **“Licences”** shall be constructed to mean any combination of two or more from the foregoing, as the context requires;

“Licensed Patents” means the Original Licensed Patents and the Additional Patent Rights;

“Liverco Improvement” means (i) all clinical data or pre-clinical toxicology data generated by or on behalf of Liverco from the Effective Date until termination of the applicable Program Licence(s) concerning the applicable Product which is the subject of the applicable terminated Program Licence(s); (ii) any regulatory filings or submissions made by Liverco until termination of the applicable Program Licence(s) in respect of the applicable Product which is the subject of the applicable terminated Program Licence(s) and, (iii) any Patent Rights filed prior to termination of the applicable Program Licence(s) by Liverco which would be infringed by the Exploitation of the applicable Product (which is the subject of the applicable terminated Program Licence(s)) to the extent that Exploitation of the same Product would also infringe any of the Patent Rights licensed to Liverco under the terminated Program Licence; in each case of (i) (ii) and (iii) above to the extent Controlled by Liverco or its Affiliates (and free from any restriction or encumbrance);

“Manufacturing Licence” has the meaning set out in Clause 2.2;

“Manufacturing Know-How” means all AAV manufacturing technologies listed in Schedule 4;

“Marketing Approval Application” or “MAA” means an application for a Marketing Approval;

“Marketing Approval” or “MA” means those Regulatory Approval(s) required by applicable laws and regulations in a particular country or territory in order to sell or commercially supply a medicinal product and/or device in that country or territory;

“Match Period” has the meaning set out in Clause 5.7;

“Materials” means Program Materials and Background Materials;

“Milestone” means a Success Milestone;

“Milestone Payment” means a Success Milestone Payment;

“Net Receipts” has the meaning in Part C of Schedule 8;

“Net Sales” has the meaning in Part A of Schedule 8;

“New Invention” means any discovery, invention (whether patentable or not), Know-How or improvement concerning [**] which (i) is of application outside the Excluded Field, and (ii) is not an Improvement and (iii) has been discovered, generated, identified or invented by AN (except in connection with his direction or supervision of the Haemostasis Group unless such work or research is in relation to isolating, characterising and/or developing a therapeutic product) and/or by any member(s) of the AN Laboratory within [**] of the Effective Date, and (iv) is Controlled by UCL or UCLB either at the time of

creation, development or generation or upon UCL or UCLB acquiring or being granted a licence to the same from the inventors or individuals responsible for the creation, development or generation of the same;

“**Non-Defaulting Party**” has the meaning set out in Clause 21.4;

“**Non-Exclusive Field**” means all uses and applications without restriction;

“**Notice Period**” has the meaning set out in Clause 21.4.1;

“**Original Licence**” means one of the Fabry Licence, FIX Licence, [**], First Serotype Licence, Promoter Licence, Manufacturing Licence, Background Licence, Program Materials Licence, the [**] and the Second Serotype Licence (if Liverco exercises its rights under Clause 2.7) and “**Original Licences**” shall be constructed to mean any combination of two or more of the foregoing, as the context requires;

“**Original Licensed Patents**” means the Fabry Patent Rights, FIX Patent Rights, the [**] Patent Rights, [**] Patent Rights, the First Serotype Patent Rights, the Promoter Patent Rights, the [**] Patent Rights, and the Second Serotype Patent Rights (if Liverco exercises its rights under Clause 2.7);

“**Original Product**” shall mean any one of a FIX Product, [**] Product, Fabry Product, [**] Product, Serotype Product or Promoter Product, and “**Original Products**” shall be constructed to mean any combination of two or more of the foregoing, as the context requires;

“**Original Program**” means one of the Fabry Program, FIX Program, [**] Program, [**] Program, First Serotype Program, Promoter Program, [**] Program, and the Second Serotype Program (if Liverco exercises its rights under Clause 2.7), and “**Original Programs**” means any combination of two or more of the foregoing, as the context requires;

“**Original Program IP**” means (i) the Fabry Program IP; (ii) the FIX Program IP, (iii) the [**], (iv) the [**], (v) the First Serotype Program IP; (vi) the Promoter Program IP; (vii) [**]; and, (viii) where the Second Serotype Option has been exercised, the Second Serotype Program IP;

“**Original Program Licence**” means one of the Fabry Licence, FIX Licence, [**] First Serotype Licence, Promoter Licence, [**], or Second Serotype Licence (if Liverco exercises its rights under Clause 2.7); and “**Original Program Licences**” means any combination of two or more of the foregoing, as the context requires;

“**Original Program Materials**” means the Program Materials falling within sections (i) to (iii) inclusive of the definition of Program Materials;

“Original Royalty Product” shall mean a Primary Royalty Product or a Secondary Royalty Product, and **“Original Royalty Products”** shall be constructed to mean any combination of the foregoing;

“Other Technology” has the meaning set out in Clause 6.3;

“Party” or “Parties” means Liverco or UCLB, or both Liverco and UCLB, as the context requires, including their respective successors in title, permitted assignees and transferees from time to time (if any);

“Patent Prosecution Costs” means those professional service fees and costs reasonably charged by a Third Party for the provision of patent filing, prosecution (including defending oppositions and interferences), maintenance and renewal services with respect to the applicable Licensed Patent, including all official fees, charges and surcharges properly incurred in the provision of such services, which services are incurred after the applicable Licence in relation to such Licensed Patent comes into force hereunder;

“Patent Rights” means all patent rights, claims in any patent right, applications for patents and the right to apply for patent rights in any part of the world including all divisionals, reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations in-part and any supplementary protection certificates or patent term extensions and where referred to in the context of a schedule hereto shall include all patent rights from time to time derived from, claiming priority from, issued or granted from those patent rights listed in such schedule;

“Primary Product” means (i) any Product that is not an Additional Royalty Product; or (ii) excluding a FIX Product or any Additional Royalty Product, any other AAV-directed gene therapy product developed by Liverco, its Affiliates and/or Sub-Licensees hereunder which is indicated for use (by way of its product label or package insert) in the treatment of Haemophilia B; or (iii) excluding [**] or any Additional Royalty Product, any other AAV-directed gene therapy product developed by Liverco, its Affiliates and/or Sub-Licensees hereunder which is indicated for use (by way of its product label or package insert) in the treatment of [**];

“Primary Royalty Product” means any Primary Product(s) (it being acknowledged that an AAV product (excluding an Additional Royalty Product) can potentially fall within more than one of the Primary Product definitions) which, in the country where sold by Liverco or its Sub-Licensee, such Primary Product:

- (i) would, were it not for the licence granted hereunder, infringe any one or more Valid Claims of any of the Original Licensed Patents in such country; or,
- (ii) is sold pursuant to a subsisting Marketing Approval granted in that country that at the time of sale has a label indication for the treatment of one or more of the diseases or conditions within the Exclusive Field and acts via a mechanism where in the case of a (a) FIX Product or other AAV-directed gene therapy product indicated for use (by way of its product label or package insert) in the treatment of Haemophilia B, it encodes [**]

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(also known as [**]), or the FIX enzyme with the following mutations [**] (b) a [**] Product or other AAV-directed gene therapy product which is indicated for use (by way of its product label or package insert) in the treatment of [**], it encodes the naturally occurring [**] (c) a Fabry Product, it encodes the naturally occurring alpha galactosidase A enzyme; or (d) [**] it encodes the naturally occurring [**] enzyme; or,

- (iii) incorporates within it or was manufactured using, the Serotype IP and/or Promoter Program IP licensed hereunder, provided that where First Serotype Program IP and/or Promoter Program IP is incorporated or used in a Primary Product, such First Serotype Program IP and/or Promoter Program IP was, as of the Effective Date, (a) included in the filing existing as of the Effective Date under the First Serotype Patent Right or Promoter Patent Rights respectively, and (b) at the time of the filing of the First Serotype Patent Right or Promoter Patent Rights, as applicable, the relevant First Serotype Program IP and/or Promoter Program IP so used was confidential and non-public; or,
- (iv) is sold pursuant to a subsisting Marketing Approval granted in that country that at the time of sale has a label indication for the treatment of one or more of the diseases or conditions within the Exclusive Field and incorporated within the Primary Product or used in its manufacture, is any of the Manufacturing Know-How or Original Program Materials which were created by AN and/or the AN Laboratory, which are licensed to Liverco hereunder and which were disclosed or transferred to Liverco by UCLB; or,
- (v) is structurally the same AAV product as that which was first administered to a human under a human clinical trial, where (a) where AN is the Principal Investigator or Liverco or a Sub-Licensee is the Sponsor of such trial or is providing the Primary Product for such trial; and, (b) [**] for that AAV product was run at the Royal Free Hospital; and, (c) such trial was directed at one or more of the diseases or conditions which form part of the Exclusive Field;

“Product” shall mean any one of a FIX Product, [**], Fabry Product, [**] Product, Serotype Product, Promoter Product, [**] and **“Products”** shall be constructed to mean any combination of two or more of the foregoing, as the context requires;

“Program” means one of the Original Programs or one of the Additional Programs, and **“Programs”** means any combination of any two or more of the foregoing, as the context requires;

“Program IP” means the Original Program IP and the Additional Program IP;

“Program Know-How” means excluding Manufacturing Know-How (i) the Know-How described in Schedule 2, Part B; (ii) to the extent not covered by (i) all Know-How, inventions and materials (together with all IP in the same) generated or developed by AN and/or the AN Laboratory under or pursuant to one or more of the Original Programs prior to the Effective Date; and (iii) with respect to the Second Serotype Program for which the Second Serotype Option is exercised, all Know-How, inventions and materials (together with all IP in the same) generated or developed by AN and/or the AN Laboratory under or pursuant to the Second Serotype Option Program at any time up to the exercise of the Second Serotype Option by Liverco;

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“Program Licence” means one of the Original Program Licences or Additional Program Licences; and **“Program Licences”** means any combination of two or more of the foregoing, as the context requires;

“Program Materials” means (i) those materials identified in Part E of Schedule 2; (ii) those materials generated or developed by AN or AN Laboratory as of the Effective Date through use of, or forming part of, the Program IP, or otherwise developed or generated by AN or AN Laboratory under or pursuant to any Program; and (iii) with respect to the Second Serotype Option Program, those materials generated or developed by AN or AN Laboratory prior to, on or after the Effective Date but up until the date of exercise of the Second Serotype Option, or forming part of, the Second Serotype Program IP, or otherwise developed or generated by AN or AN Laboratory under or pursuant to the Second Serotype Program IP; and (iv) with respect to the Additional Programs, those materials identified in part F of Schedule 2 under the title Additional Program Materials;

“Promoter Licence” has the meaning set out in Clause 2.4.5;

“Promoter Patent Rights” means (i) those patent applications listed in Part A of Schedule 2 under the title ‘Promoter Patents’ and all Patent Rights derived therefrom; and (ii) any Future Patents filed in respect of HLP2, and/or any of the Program Know-How identified in (ii) of the definition of Promoter Program IP;

“Promoter Product” means, excluding any Additional Royalty Product, any AAV gene therapy product which is covered by, incorporates in it or uses in its manufacture any of the Promoter Program IP licensed to Liverco hereunder;

“Promoter Program” means the program of research as conducted prior to the Effective Date and resulting in patent applications listed in Part A of Schedule 2 under the title ‘Promoter Patents’;

“Promoter Program IP” means means the Promoter Patent Rights, and (ii) Program Know-How existing at the Effective Date applicable to HLP2 and Exploitation thereof;

“[] Method”** means any method or material that has been provided to the AN Laboratory by [**];

“Purple Book Reference” has the meaning set out in Clause 15.9;

“Quarterly” or “Quarter” a period of three calendar months each ending on 31 March, 30 June, 30 September or 31 December;

“Recipient Party” has the meaning set out in Clause 17.1;

“Referral Notice” has the meaning set out in paragraph 1 of Part B Schedule 8;

“Regulatory Approval” any and all approvals (including any applicable supplements, amendments, pre and post approvals, and approvals of applications for regulatory exclusivity), licenses, registrations, or authorisations of any federal, national, multinational, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity necessary for the manufacture, distribution, use, testing, development, storage, import, export, transport, promotion, marketing and sale of a medicinal product in a country or countries;

“Regulatory Authority” any governmental or regulatory authority responsible for assessing and/or granting Regulatory Approvals (including any ethics committees) and **“Regulatory Authorities”** shall mean more than one such authority;

“Regulatory Exclusivity” means on a country by country basis that a Third Party under applicable laws concerning the application for and grant of Marketing Approvals having jurisdiction over that country at the relevant time (i) is precluded from submitting a Marketing Approval Application for any Competitive Product; or (ii) in respect of any Competitive Product, is prohibited from relying upon Liverco’s, or its Affiliates’ or Sub-Licensee’s product dossier or Regulatory Submission (from which such party obtained a Marketing Approval) concerning any Royalty Product, under any applicable abridged or streamlined procedure to obtain a Marketing Approval for such Competitive Product;

“Regulatory Submission” in respect of a Royalty Product, the package or packages of data, pre-clinical and clinical trial data and materials, information, results, materials and samples (including any Test and Regulatory Data and/or the drug master file or part thereof) submitted to a Regulatory Authority in support of a Marketing Approval Application or any other Regulatory Approval;

“Responsible Patents” has the meaning set out in Clause 15.4.2;

“Royalty” or **“Royalties”** has the meaning set out in Clause 12.1;

“Royalty Expiry” has the meaning set out in Clause 12.6;

“Royalty Product” shall mean any Original Royalty Products or any Additional Royalty Products, and **“Royalty Products”** shall be constructed to mean any combination of the foregoing;

“Royalty Term” has the meaning set out in Clause 12.13;

“Secondary Royalty Product” means any product (including an AAV product) but not a Primary Product or Additional Royalty Product, where such product when sold in a country by Liverco or its Sub-Licensee, (i) would, were it not for the Licences granted hereunder in respect of the Original Licensed Patents, infringe any one or more Valid Claims of any of the Original Licensed Patents in such country; or (ii) utilises in its manufacture (a) the [**] as identified in Schedule 4 or a suspension cell line, as disclosed and licensed to Liverco

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hereunder as comprised in the Manufacturing Know-How, provided that such method, in its entirety, is confidential to AN, the AN Laboratory and/or UCLB as of the Effective Date, or (b) any Program Materials supplied by UCLB to Liverco hereunder;

“**Second Serotype Exercise Period**” has the meaning set out in Clause 2.7;

“**Second Serotype Licence**” has the meaning set out in Clause 2.8;

“**Second Serotype Licence Notice**” has the meaning set out in Clause 2.7;

“**Second Serotype Option**” means Liverco’s rights under Clause 2.7 and 2.8;

“**Second Serotype Patent Rights**” any Patent Rights filed by or on behalf of UCLB from time to time in respect of (i) any work undertaken by AN and/or the AN Laboratory prior to, on or after the Effective Date under or pursuant to the Second Serotype Program as set out in Schedule 1; and (ii) any Program Know-How identified in (ii) of Second Serotype Program IP

“**Second Serotype Product**” means, excluding any Additional Royalty Product, any AAV directed gene therapy product which is covered by, uses in its manufacture or incorporates in it any of the Second Serotype Program IP licensed to Liverco hereunder;

“**Second Serotype Program**” means the program of research relating to novel AAV serotypes generated, developed or used by AN and/or the AN Laboratory for liver directed AAV therapy, defined in Schedule 1 under the title Second Serotype Program conducted prior to the Effective Date together with the program of research conducted after the Effective Date as described in Schedule 1 under the title Part B: Second Serotype Project Plan;

“**Second Serotype Program IP**” means (i) Second Serotype Patent Rights; and (ii) Program Know-How existing at the date of exercise of the Second Serotype Option applicable to the serotypes isolated from, and/or designed and/or made as part of the Second Serotype Program or Covered by any of the Second Serotype Patent Rights, and their Exploitation thereto;

“**Serotype IP**” means the First Serotype Program IP and, where the Second Serotype Option is exercised, the Second Serotype Program IP;

“**Serotype Product**” means, excluding any Additional Royalty Product, any AAV directed gene therapy product which is covered by, uses in its manufacture or incorporates in it any of the Serotype IP licensed to Liverco hereunder;

“**SPC**” has the meaning set out in Clause 15.8;

“**SSA**” means the Subscription and Shareholders’ Agreement between Liverco, UCLB, Prof. Amit Nathwani, and [**] dated as of the Effective Date;

[**]

“**Sub-Licensee**” means any person (including an Affiliate of Liverco) to whom Liverco sub-licenses all or part of the Intellectual Property licensed to it under this Agreement; “**Success Milestone**” has the meaning set out in Clause 11.1;

“**Success Milestone Payment**” has the meaning set out in Clause 11.1;

“**Surrender**” or “**Surrendered**” in respect of any Patent Rights, any of (i) ceasing to maintain (by payment of renewal fees or otherwise) the applicable Patent Rights; (ii) withdrawing, surrendering, dedicating to the public or allowing the applicable Patent Rights to lapse; (iii) in the case of a pending application de-designating, or not validating or ratifying in, a country covered by the application or not entering into the national or regional phase in a country designated in the international or convention application or (iv) consenting to or ceasing to defend an application, action or litigation for revocation;

“**[**] Licence**” has the meaning set out in Clause 2.4.10;

“**[**] Patent Rights**” means patent application to be filed based on the draft specification emailed from [**] together with the invention disclosed therein and all Patent Rights derived therefrom;

“**[**] Product**” means any AAV-directed gene therapy product that is not an Original Product and which is indicated (by way of its product label or package insert) for use in the amelioration, treatment and/or diagnosis of [**] and which would be infringed by any of the [**] Patent Rights but for the licence granted to Liverco hereunder;

“**[**] Program**” means the program of research defined in Schedule 1 under the title [**] Program as conducted prior to the Amendment Date;

“**[**] Program IP**” means (i) the [**] Patent Rights; and (ii) excluding Manufacturing Know-How, all Know-How described in Part F of Schedule 2 under the title [**] Program Know How; and (iii) the materials listed in Part F of Schedule 2 under the title [**] Materials (together with all IP in the same);

“**Technology**” collectively means Program IP, Manufacturing Know-How, UCL Background IP and the Materials;

“**Term**” has the meaning in Clause 21.1;

“**Territory**” all countries throughout the World;

“**Third Party**” any person other than the Parties or their respective Affiliates or AN;

“**Third Party Access Rights**” has the meaning set out in Clause 12.8;

“**TP Fees**” has the meaning set out in Clause 12.8;

“**UCL**” University College London, an institution incorporated in the United Kingdom by Royal Charter and having its address at Gower Street, London, WC1E 6BT;

“**UCL Background IP**” means (i) the Know-How listed in Part A of Schedule 3; and (ii) excluding Program IP, Program Know-How, Manufacturing Know-How, the [**] and Know-How relating to the use of HLP1 Promoter Sequence in connection with any [**] Product, all other Know-How generated by AN and/or the AN Laboratory and/or used by AN and/or the AN Laboratory pursuant to or in conjunction with any of the Programs (or any combination of, or across any of, the Programs) and which is Controlled by UCLB as of the Effective Date, or in relation to the Second Serotype Option Program is Controlled by UCLB at any time during the period from the Effective Date until the date of exercise of the Second Serotype Option, or in relation to the Additional Programs is Controlled by UCLB at any time during the period prior to the Amendment Date; and (iii) any Patent Rights Controlled by UCLB from time to time in respect of any of the Know-How identified under (i) or (ii) above and/or the Background Materials;

“**Unresolved Matter**” has the meaning set out in Clause 30.2;

“**Valid Claim**” means a claim within (i) an issued or granted and unexpired Patent Right, including any Licensed Patent; or (ii) a pending application for a Patent Right including an application with respect to any Licensed Patents, which has not been pending for more than [**] from the date of the priority filing from which such pending application originates, and in each case of (i) and (ii) above, which has not been held unenforceable, unpatentable or invalid by a decision of a court or government body of competent jurisdiction, or where appealed within the time allowed for appeal has not been held unenforceable, unpatentable or invalid by an appellate body of competent jurisdiction (including by the highest appellate court in the relevant jurisdiction where appealed to that court), or, which has not been withdrawn, cancelled, revoked, disclaimed, or rendered unenforceable through disclaimer or otherwise, or which has not been donated or dedicated to the public. Surrendered or which has not been deemed invalid by an interference or opposition panel or court as part of any interference or opposition proceeding;

“**Year**” a period of twelve (12) months commencing on 1 January;

1.2 In this Agreement, unless the context requires otherwise:

1.2.1 use of the singular includes the plural and vice versa and use of any gender includes the other genders;

1.2.2 any reference to “**this Agreement**” is a reference to this Agreement as from time to time amended, varied or extended in any way; and,

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

- 1.2.3 **“undertaking”** shall have the meaning given by section 1161 Companies Act 2006 save that for the purposes of this Agreement and for the avoidance of doubt, an undertaking shall include a limited liability partnership.
- 1.3 In this Agreement unless otherwise specified:
- 1.3.1 any reference to a recital, clause, paragraph or schedule is to the relevant recital, clause, paragraph or schedule of or to this Agreement, and any reference in a schedule to a part or a paragraph (as opposed to a clause) is to a part or a paragraph of that schedule;
- 1.3.2 any reference to a **“person”** includes an individual, firm, partnership, body corporate, corporation, association, organisation, government, state, foundation and trust, in each case whether or not having separate legal personality;
- 1.3.3 **“parent undertaking”** and **“subsidiary undertaking”** shall have the respective meanings given by section 1162 Companies Act 2006 save that for the purposes of this Agreement, an undertaking shall be treated as a member of another undertaking if any of the shares in that other undertaking are registered in the name of another person (or its nominee) as security (or in connection with the taking of security) from the first undertaking or any of that first undertaking’s subsidiary undertakings;
- 1.3.4 any reference to a statute, statutory provision or subordinate legislation (**“legislation”**) shall be construed as referring to that legislation as amended and in force from time to time and to any legislation which re-enacts, re-writes or consolidates (with or without modification) any such legislation;
- 1.3.5 any reference to an English legal term or concept or any court, official, governmental or administrative authority or agency in England includes, in respect of any jurisdiction other than England, a reference to whatever most closely approximates in that jurisdiction to the relevant English legal term;
- 1.3.6 any reference to an agreement includes any form of arrangement, whether or not in writing and whether or not legally binding;
- 1.3.7 **“writing”** shall include any modes of reproducing words in a legible and nontransitory form excluding (unless expressly stated to include) email, SMS and other temporary transient electronic messaging systems and **“written”** shall be construed accordingly; and,
- 1.3.8 a period of time being specified which dates from a given day or the day of an act or event, it shall be calculated exclusive of that day.
- 1.4 In this Agreement, the words “other”, “including”, “includes”, “include”, “in particular” and any similar words, shall not limit the general effect of words that precede or follow them and accordingly, the *ejusdem generis* rule shall not apply.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 1.5 Any undertaking by or obligation on a Party not to do any act or thing includes an undertaking not to allow, cause or assist the doing of that act or thing and to exercise all rights of control over the affairs of any other person which that Party is able to exercise (directly or indirectly) in order to secure performance of that undertaking, which in the case of UCLB shall include UCL as a person over whom UCLB can exercise control.
- 1.6 The index to and the headings in this Agreement are for information only and are to be ignored in construing the same.
- 1.7 Where this Agreement refers to a Person being “free” to do something, this shall be construed as that Person not being prevented, whether by law, equity or contract, from doing that thing.

2. LICENCE GRANT

UCL Background Licence

- 2.1 Subject to Clause 4, UCLB hereby grants to Liverco (i) with effect from the Effective Date for the full duration of the Term and throughout the Territory a licence to the UCL Background IP and Background Materials existing as of the Effective Date (including the right to sub-license through multiple tiers) and (ii) with effect from the Amendment Date for the full duration of the Term and throughout the Territory a licence to the UCL Background IP and Background Materials created after the Effective Date but prior to or on the Amendment Date (including the right to sub-license through multiple tiers); in each case of (i) and (ii) above:
 - 2.1.1 within the Exclusive Field to use the same for any and all acts of Exploitation, which licence shall be exclusive to Liverco (to the exclusion of UCLB, UCL and any Third Party); and
 - 2.1.2 without prejudice to Clause 2.1.1 (such that Liverco retains exclusivity in the Exclusive Field for the duration of the licence granted thereunder) within the Non-Exclusive Field (other than with respect [**]) for any other purpose or act of Exploitation without restriction, which licence shall be non-exclusive, royalty-free, irrevocable and perpetual,

(collectively the “**Background Licence**”).

The Background Licence shall be assignable as part of any assignment of this Agreement in accordance with Clause 26. Liverco shall not be entitled to assign the Background Licence independently of the other Licences.

Manufacturing Know-How

- 2.2 Subject to Clause 4, UCLB hereby grants to Liverco with effect from the Effective Date and for the full duration of the Term and throughout the Territory a licence to the Manufacturing Know-How (including the right to sub-license through multiple tiers):

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 2.2.1 within the Exclusive Field to use the same for any and all acts of Exploitation, which licence shall be exclusive to Liverco (to the exclusion of UCLB, UCL and any Third Party); and
- 2.2.2 without prejudice to Clause 2.2.1 (such that Liverco retains exclusivity in the Exclusive Field for the duration of the licence granted thereunder), within the Non-Exclusive Field for any other purpose or act of Exploitation without restriction, which licence shall be non-exclusive, irrevocable and perpetual;

(collectively the “**Manufacturing Licence**”).

The Manufacturing Licence shall be assignable as part of any assignment of this Agreement in accordance with Clause 26. Liverco shall not be entitled to assign the Manufacturing Licence independently of the other Licences,

Impact of Second Serotype Option

- 2.3 It is acknowledged that the Background Licence granted under Clause 2.1.1 and the Manufacturing Licence granted under Clause 2.2.1 (and the exclusive rights respectively therein) shall include Exploitation of (i) the Second Serotype Product upon election of the Second Serotype Option to the extent it is within the Exclusive Field, but failure to exercise the Second Serotype Option shall not effect or limit the licence granted under Clause 2.1.1 or 2.2.1; and (ii) the Additional Royalty Products.

Program Licences

- 2.4 Subject to Clause 4, UCLB hereby grants to Liverco throughout the Territory an exclusive licence (to the exclusion of UCLB, UCL and any Third Party) which shall be sublicensable through multiple tiers:
 - 2.4.1 with effect from the Effective Date and for the full duration of the Term, to the Fabry Program IP for any act of Exploitation concerning any product, therapy, service **or** process without restriction or field limitation (the “**Fabry Licence**”);
 - 2.4.2 with effect from the Effective Date and for the full duration of the Term, to the FIX Program IP for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the “**FIX Licence**”);
 - 2.4.3 with effect from the Effective Date and for the full duration of the Term, to the [**] for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the [**]);
 - 2.4.4 with effect from the Effective Date and for the full duration of the Term, to the [**] for any act of Exploitation concerning any product, therapy, service of process without restriction or field limitation (the [**]);
 - 2.4.5 with effect from the Effective Date and for the full duration of the Term, to the Promoter Program IP to use the same for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the “**Promoter Licence**”);

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- 2.4.6 with effect from the Effective Date and for the full duration of the Term, to the First Serotype Program IP to use the same for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the “**First Serotype Licence**”);
- 2.4.7 with effect from the Effective Date (in respect of those identified in (i) to (iii) of the definition of Program Materials) and with effect from the Amendment Date (in respect of those identified in (iv) of the definition of Program Materials) and in each case for the full duration of the Term, to the Program Materials to use the same for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the “**Program Materials Licence**”); and
- 2.4.8 with effect from the Effective Date and for the full duration of the Term, to the [**] to use the same for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the [**]);
- 2.4.9 with effect from the Amendment Date and for the full duration of the Term, to the [**] to use the same for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (“**[**] Licence**”); and,
- 2.4.10 with effect from the Amendment Date and for the full duration of the Term, to the [**] to use the same for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (the [**]);

it being acknowledged that each of the foregoing Licences granted under this Clause 2.4 (i) may only be revoked or terminated pursuant to a right of termination under Clause 9.10 or Clause 21 in respect of the applicable Licence(s); and (ii) may all be assigned together (but not individually) as part of any assignment of this Agreement in accordance with Clause 26.

- 2.5 Subject to Clause 4 and without prejudice to Clause 2.4 (such that Liverco retains exclusivity for the duration of the licences granted thereunder), UCLB hereby grants to Liverco for the full duration of the Term and throughout the Territory a non-exclusive licence, which shall be sub-licensable through multiple tiers, to the Program Know-How and the Program Materials for any act of Exploitation concerning any product, therapy, service or process in the Non-Exclusive Field.

UCLB’s Obligations to procure a licence to HLP1 Promoter Sequence and certain data

- 2.6 UCLB, AN and [**] have an ongoing relationship relating to and concerning technology and clinical trials that is relevant to the Exclusive Field and the technology licensed hereunder, including UCLB and [**] being joint owners of the HLP1

Promoter Sequence. Recognising the importance of such technology and clinical trial data to Liverco's exploitation of the technology hereunder, with effect from the Effective Date UCLB shall:

- 2.6.1 use Best Endeavours (which will include having AN and/or UCLB management, but not any other UCL staff, participate in negotiations and discussions with [**]) to
 - 2.6.1.1 procure, in consultation with Liverco, the grant to Liverco of a licence to the HLP1 Promoter Sequence (including those Patent Rights co-owned by [**] claiming the HLP1 Promoter Sequence), and UCLB shall propose to [**] a licence to substantially reflect the form set out in Part A of Schedule 11 ; and,
 - 2.6.1.2 facilitate, in consultation with Liverco, the grant to Liverco of a licence on fair and commercial terms to use the [**] as more clearly identified in Part B of Schedule 11, it being understood that Liverco shall be responsible for negotiating the terms of any such licence, at its sole discretion with [**];
- 2.6.2 use commercially reasonable endeavours (which will include having AN and/or UCLB management, but not any other UCL staff, participate in negotiations and discussions with [**]) to facilitate, in consultation with Liverco, (i) access for Liverco to the [**]; and (ii) [**]; it being understood in each case that Liverco shall be responsible for negotiating the terms of such access and agreement, at its sole discretion with [**].

Option to a Licence under the Second Serotype Program IP

- 2.7 UCLB shall procure that AN and the AN Laboratory shall use commercially reasonable efforts to promptly carry out and conclude the Second Serotype Program and deliver the Final Written Report regarding the Second Serotype Program. At any time [**] following Liverco's receipt of the Final Written Report concerning the Second Serotype Program in accordance with the Second Serotype project plan set out in Schedule 1 ("**Second Serotype Exercise Period**"), Liverco shall have the right upon written notice to UCLB, to exercise its option for the grant of a licence on the terms of this Agreement to the Second Serotype Program IP ("**Second Serotype Licence Notice**"). Prior to service of a Second Serotype Licence Notice:
 - 2.7.1 UCLB shall keep Liverco informed, on a reasonably frequent basis {or otherwise upon request by Liverco), of (i) the status and performance of the Second Serotype Program against the Second Serotype project plan set out in Schedule 1; (ii) developments and advancements in the Second Serotype Program since the last report; (iii) identification and disclosure of any Second Serotype Program

- IP not previously disclosed to Liverco; (iv) disclosure at least [**] in advance of filing of any draft patent filing for any Second Serotype Patent Rights Intended to be filed; and (v) details of all Second Serotype Patent Rights that have been filed and their current prosecution status;
- 2.7.2 Liverco shall have the right {prior to filing and thereafter) to participate with UCLB and input into any draft patent filing for any Second Serotype Patent Rights that are filed or are intended to be filed and UCLB shall consider, take into account and implement any reasonable recommendations made by Liverco with respect to such filings or proposed filings;
- 2.7.3 UCLB shall use reasonable endeavours to seek appropriate IP protection for any results and inventions arising from the Second Serotype Program;
- 2.7.4 UCLB shall, and shall procure that UCL shall, ensure that all Intellectual Property generated by AN or the AN Laboratory in connection with the Second Serotype Program shall be owned by UCLB and shall be held subject to the terms of this Agreement; and,
- 2.7.5 UCLB shall not, and shall procure that UCL shall not, assign, grant (whether conditional, option or otherwise) any rights to, encumber, charge, mortgage, license, sell, Exploit or waive any rights over any of the Second Serotype Program IP nor enable another to do so.
- 2.8 Automatically upon service of a Second Serotype Licence Notice by Liverco, UCLB shall have granted to Liverco for the remaining duration of the Term (from the date of such notice) and throughout the Territory, an exclusive (to the exclusion of UCLB, UCL and any Third Party) licence which shall be sub-licensable through multiple tiers to the Second Serotype Program IP for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation (collectively the **“Second Serotype Licence”**). Upon the grant of the Second Serotype Licence, the licences to UCL Background IP, Background Materials, Manufacturing Know-How and Program Know-How shall automatically apply to Second Serotype Products, the relevant schedules in respect of Patent Rights shall be updated and the licence under Clause 2.5 shall include Program Know-How in relation to the Second Serotype Program. The Second Serotype Licence (i) may only be revoked or terminated pursuant to a right of termination under Clause 9.10 in respect of the Second Serotype Licence or Clause 21; and (ii) may be assigned but only as part of the assignment of this Agreement in accordance with Clause 26.
- 2.9 If Liverco does not serve a Second Serotype Licence Notice on UCLB prior to expiry of the Second Serotype Exercise Period, thereafter without otherwise affecting any other Licences, including in each case the exclusivity granted or to be granted in respect of the same, Liverco shall cease to have any right or interest in or to the Second Serotype Program IP referred to in Clause 2.7 and UCLB shall, subject to the other Licences hereunder, be free to develop and exploit the Second Serotype Program IP as it thinks fit, without any reference to Liverco.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 2.10 Upon exercise of the Second Serotype Option (if any) the Parties shall, purely for convenience and future reference purposes, co-operate to agree a list of Know-How and materials generated after the Effective Date that are included in the relevant Second Serotype Licence. The grant of the Second Serotype Licence is not dependent on agreeing such list, and such list shall not fetter, vary or otherwise limit the terms of this Agreement or the scope or inclusion of Know-How or materials under the Licence unless the Parties expressly agree in writing that it shall do.

UCLB Grant Back

- 2.11 Whilst AN is employed by UCL and provided that any use made by UCL, AN and/or UCLB of the [**] has been in compliance with the provisions of this Agreement, including Clause 4 and 6.5, if AN has made use of any of the [**] hereunder in the Excluded Field and in order to exploit the technology developed in the Excluded Field it is necessary to license such [**] to a Third Party in combination with other patented technology, then UCLB shall have the right to discuss with Liverco reasonable royalty bearing commercial terms for a licence to such [**] provided that Liverco shall have sole discretion as to whether or not to grant any such licence. The foregoing shall not prevent Liverco from granting Third Parties any exclusive rights in accordance with Clause 3 to any of the [**] licensed to it under this Agreement.

FX Codon Optimisation sequence

- 2.12 UCLB hereby grants to Liverco throughout the Territory an exclusive licence {to the exclusion of UCLB, UCL and any Third Party) which shall be sub-licensable through multiple tiers with effect from the Effective Date and for the full duration of the Term, to the FX Vector and FX Vector IP for any act of Exploitation concerning any product, therapy, service or process without restriction or field limitation ("**FX Vector licence**"). The FX Vector Licence (i) may only be revoked or terminated pursuant to a right of termination under Clause 21 in respect of the applicable Licence; and (ii) may all be assigned together as part of any assignment of this Agreement in accordance with Clause 26.

[**]

- 2.13 UCLB shall collaborate and co-operate in good faith with Liverco to (i) agree upon the final form of the [**] Patent Right to be filed as a priority filing in the name of UCLB after the Amendment Date; and, (ii) draft and file the [**] Patent Right as soon as reasonably possible, which for the avoidance of doubt will, in each case, automatically be deemed included in the licence granted under clause 2.4 upon their respective filing. The costs of such filings shall be subject to the provisions of Clause 15.5.1.

3. SUB-LICENSING

- 3.1 Other than to a Tobacco Party, Liverco shall be entitled to sub-license any of the Technology licensed to it hereunder {which includes the right to transfer any Materials) through multiple tiers and without restriction save that UCLB shall have a right to object to the grant of a sub-license by Liverco to other Third Parties solely in the following specific circumstances:

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 3.1.1 UCLB may only object in respect of a proposed sub-licensee if, due to the nature of that proposed sub-licensee's business, the grant of the sub-license to that entity will, in the reasonable and measured opinion of UCLB, [**]; and
 - 3.1.2 if the circumstances in Clause 3.1.1 apply, UCLB shall only have the right to object provided that it serves written notice of its objection setting out the grounds for its objection within [**] of written notice from Liverco of the identity of the proposed sub-licensee.
- 3.2 If UCLB has objected to the grant of a sub-license in accordance with Clause 3.1, Liverco may either accept that objection and not grant (or terminate) the sub-license or if it disputes the objection the following shall apply:
- 3.2.1 UCLB shall procure that representatives from UCLB and UCL shall meet with Liverco [**] of the objection to enable the Parties and UCL to discuss the proposed sub-license and the reasons for the perceived risk that an association will have a [**] and, in good faith, seek ways in which to overcome or mitigate such risk to a pragmatic and reasonably acceptable position;
 - 3.2.2 if UCLB agrees that the risk is acceptable or UCLB and Liverco agree on any conditions to include in a sub-license to avert or mitigate the risk then Liverco shall be entitled to grant (or maintain) the sub-license subject to any agreement reached between UCLB and Liverco:
 - 3.2.3 if within [**] of the objection, (i) UCLB and Liverco are unable to reach an agreement and Liverco still wishes to grant (or maintain) a sub-license or (ii) representatives of UCLB and UCL do not or are unable to meet with Liverco; then Liverco shall be entitled to refer the objection to a person nominated by the chairman of [**] for the determination identified below (the **"Appointed Expert"**). The nomination shall be subject to the Appointed Expert agreeing to be so appointed and the terms of that appointment set by the [**]. The costs of the Appointed Expert shall be borne by the Parties equally. The Appointed Expert shall be entitled to consider any information presented to the Appointed Expert by UCLB or Liverco (provided that each Party shall copy to the other Party all information provided to the Appointed Expert at the same time) and any other information that the Appointed Expert may consider relevant. The Appointed Expert shall make his or her decision as expert and not as arbiter, and the decision of the Appointed Expert shall be final and binding save in the case of manifest error. If, in the Appointed Expert's opinion the Appointed Expert considers the grant of a sub-license to the Third Party objected to by UCLB will, by virtue of the nature of the business of that Third Party entity, [**], then Liverco shall not grant (or shall terminate) such sub-license. In all other circumstances, irrespective of any

objection by UCLB or UCL, Uverco shall be entitled to grant (or maintain) the sub-licence without restriction or condition. UCLB and Liverco hereby irrevocably agree, accept and acknowledge that neither the [**], [**] the Appointed Expert shall have any liability to UCLB or Liverco (or any Third Party or any other person) by virtue of the provisions of this Clause or exercise of decisions pursuant this Clause, and UCLB and Liverco hereby undertake not to make or bring any claim against any of the [**] the Appointed Expert with respect to performance in connection with the foregoing or this Agreement.

- 3.3 In so far as Liverco grants a sub-licence of rights under the Technology to a Sub-Licensee (other than in respect of a material transfer agreement, contract research agreement or manufacturing agreement, provided they do not include rights to sell products or services incorporating the Technology) ("**Commercial Licence**"), Liverco shall in such circumstances enter into a written agreement with each sub-licencee (provided that this obligation to enter into a written agreement shall not apply where, and for so long as, the Sub-Licensee is an Affiliate of Liverco). Additionally,
- 3.3.1 Liverco shall ensure that the provisions of the sub-licence agreement do not grant rights in the Technology beyond those granted hereunder and impose obligations and restrictions on the Sub-Licensee consistent with the obligations and restrictions imposed on Liverco hereunder under (i) Clauses 3, 13 and 17 and (ii) Clauses 22.1.1 and 22.2 to 22.4;
- 3.3.2 Liverco shall ensure that the sub-licence agreement imposes obligations of confidentiality on the Sub-Licensee which are no less onerous than those set out in Clause 17;
- 3.3.3 the sub-licence agreement shall, if required by Liverco, be novated to UCLB (which novation UCLB will accept) on termination of this Agreement, provided that (i) the Sub-Licensee is willing to accept the novation of any sub-licence agreement upon such termination and make payment of sums otherwise payable under this Agreement for the Sub-Licensee's (and its sub-sublicensees') Exploitation of the Technology directly to UCLB; (ii) at the time of novation the Sub-Licensee is not in breach of its obligations to Liverco under the sub-licence agreement; (iii) the sub-licence agreement does not impose on UCLB any obligations or commitments beyond those included in this Agreement; and (iv) the sub-licence agreement includes terms (at a minimum) consistent with those in Clauses 3, 9, 11, 12, 13, 17, 20, 21.4, 21.5, 21.6, 21.7 and 21.8 of this Agreement failing which the sub-licence agreement shall automatically terminate.
- 3.4 Liverco shall be liable to UCLB for all acts and omissions of its Sub-Licensees (other than those whose sub-licence has novated to UCLB) that, if committed by Liverco, would constitute a breach of any of the provisions of this Agreement.
- 3.5 Liverco shall provide UCLB with written notice of any Commercial Licence and, to the extent it is able to do so, provide UCLB with a copy of any Commercial Licence (with confidential and financial information redacted) promptly following its execution.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 3.6 Notwithstanding the above, where the sub-licence relates only to UCL Background IP or Manufacturing Know-How the provisions of Clauses 3.3.1, 3.3.3, and 3.5 shall not apply and such sub-licences shall not terminate on termination of this Agreement.
- 3.7 For the purposes of this Clause 3, “**Tobacco Party**” means: (i) any entity which develops, sells or manufactures tobacco products; and/or (ii) any entity which makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products. Furthermore, Tobacco Party shall include any entity that is controlled by or controls any entity referred to in (i) or (ii); controlled and controls having the meaning defined in the definition of Affiliate.

Sub-Licensee Payments

- 3.8 If Liverco, grants a sub-licence of any [**] (including at least one of the [**]) to a Sub-Licensee that is a Third Party for the right to commercialise a [**] prior to the earlier of (i) [**] of a patient in a [**] clinical trial (carried out by Liverco) using any AAV-directed gene therapy product targeted at the treatment of [**] or or (ii) [**] (carried out by Liverco) of any AAV-directed gene therapy product targeted at the treatment of [**] or (iii) Liverco receives, in aggregate, funds by way of investment (whether through equity, debt or other financing) [**], (such sub-licence being a “**Sublicence**”), and Liverco receives in consideration of that Sublicence grant any Net Receipts, Liverco shall, subject to Clause 13, make payments to UCLB from time to time calculated by reference to [**] of Net Receipts received by Liverco under that Sublicence (“**Sublicence Payment**”). No Sublicence Payment shall be due in respect of the licensing by Liverco of any other Technology beyond the [**].
- 3.9 Each Sublicence Payment under Clause 3.8 is subject to the following:
- 3.9.1 where the Sublicence includes a grant of rights to Intellectual Property which is not [**], then for the purposes of calculating the Sublicence Payment, the value of Net Receipts shall be adjusted to a value attributable to the [**] sub-licensed to the Sub-licensee which will be calculated in direct proportion to the value fairly and reasonably attributed [**] licensed hereunder as against all other Intellectual Property licensed to the Third Party under the Sublicence. At UCLB’s request Liverco shall provide details to UCLB of the basis of any proposed apportionment and either party may refer any dispute relating to such apportionment to the Expert in accordance with Part C of Schedule 8;
- 3.9.2 Sublicence Payments in respect of Net Receipts received under a particular Sublicence shall, on a country by country basis, cease to be payable upon the later of (i) the expiry of the last Valid Claim of the [**] in that country; or (ii) [**] after the Effective Date.

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3.10 In the event that any of the Milestones are achieved by a Sub-Licensee (as opposed to by Liverco) in respect of a particular [**] then Liverco shall be entitled to offset against the corresponding Milestone Payment payable to UCLB the amount of Sublicence Payments payable to UCLB in respect of a Sublicence to that [**] on or before the date that the Milestone Payment is triggered. In the event that any Milestone Payment is triggered by a second or subsequent Royalty Product (derived from [**]), the right to offset Sublicence Payments against such Milestone Payment shall exclude any previous Sublicence Payments to the extent that they have already been offset in relation to the previous Milestone Payment provided that any excess of a Sublicence Payment not offset shall be capable of offset against future Milestone Payments relating to [**] derived from [**]. Where the amount of the Milestone Payment exceeds the Sublicence Payments that can be offset against it, Liverco shall pay to UCLB the shortfall against that Milestone Payment in accordance with Clause 11.

4. RETAINED RIGHTS, ACADEMIC RESEARCH & RESTRICTIONS

4.1 The licences to Program IP, the Background Licence and the Manufacturing Licence, to the extent each of them are exclusive (including the Second Serotype Program IP), are subject to UCLB reserving for, and having the right to grant the limited non-assignable, worldwide, perpetual and irrevocable right to, UCL to enable UCL to use the (i) licensed Program IP; (ii) the UCL Background IP and Background Materials forming part of the exclusive licence pursuant to Clause 2.1.1, and/or (iii) the Manufacturing Know-How forming part of the exclusive licence pursuant to Clause 2.2 .1 , solely to undertake Academic Research at UCL and/or (subject to Clause 4.5) in collaboration with other Academic Organisations, and for no other purposes (the “Academic Rights”). Notwithstanding the foregoing, in respect of the Additional Program IP, the Academic Rights are limited to the right for AN and the AN Laboratory alone to use the Additional Program IP solely to undertake Academic Research at UCL, and such Additional Program IP shall not be disclosed or licensed to a Third Party including any Academic Collaborator except that disclosure to an Academic Collaborator, to an academic based with UCL or to a Funder under terms of confidentiality is permissible. For the avoidance of doubt, but subject to Clause 7.7.1, UCLB and/or UCL (including AN and AN laboratory) are not precluded under this Clause 4, from using and/or disclosing for any purpose without any restriction, the UCL Background IP, the Background Materials and Manufacturing Know-How outside of the Exclusive Field.

4.2 The Academic Rights shall be subject to the following:

4.2.1 UCLB and UCL shall not, without the prior written consent of Liverco, be entitled to apply for, obtain or use funding from a Third Party other than a Funder;

4.2.2 UCLB and UCL shall be entitled to apply for, obtain and use Third Party funding from a Funder for any of the Academic Research, provided that:

- (i) during the Improvement Period only and where the Academic Research relates to or is likely to give rise to Improvements, UCLB and UCL shall be entitled to accept such Third Party funding if there are no restrictions or conditions on UCLB and UCL by the Third Party Funder with respect to Exploitation of the funded Improvements; and

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(ii) during the Improvement Period only and where the Academic Research relates to or is likely to give rise to Improvements, UCLB and UCL shall not without the prior written consent of Liverco (which consent shall not be unreasonably withheld) accept any such funding if such Third Party Funder imposes restrictions or conditions on the Exploitation of Improvements funded in whole or in part by that Third Party;

4.2.3 UCLB shall and shall procure that UCL shall maintain the confidentiality of the Program IP (with the exception of information disclosed in the Licensed Patents once published) and shall impose the same restrictions on its Academic Collaborators (and enforce the same), save that UCL and its Academic Collaborators shall be entitled to publish the results of their Academic Research under these Academic Rights subject to and in accordance with the provisions of Clause 4.3;

4.2.4 with the exception of academic clinical studies permitted under Clause 4.2.5, no studies intended to be (or required by applicable laws, ethical requirements or standards or otherwise to be) conducted in accordance with the standards of GLP (good laboratory practice), GMP (good manufacturing practice) and/or GCP (good clinical practice) may be conducted under the Academic Rights without the prior written consent of Liverco (such consent not to be unreasonably withheld having regard to Liverco's commercial considerations and its assessment of the risk/benefit to the patient associated with any proposed study), and UCLB shall procure that an equivalent restriction is imposed on and complied with by all Academic Collaborators and shall ensure that the Program Materials and Background Materials (that are subject to the exclusive licence granted pursuant to Clause 2.4.7 and 2.1.1 respectively) are not provided to any Third Party for the purposes of any such study that has not been authorised by Liverco;

4.2.5 no clinical studies or treatment of patients may be conducted under the Academic Rights without the prior written consent of Liverco (such consent not to be unreasonably withheld having regard to Liverco's commercial considerations and its assessment of the risk/benefit to the patient associated with any proposed study or treatment of patients), and UCLB shall procure that an equivalent restriction is imposed on and complied with by all Academic Collaborators and shall ensure that the Program Materials and Background Materials (that are subject to the exclusive licence granted pursuant to Clause 2.4.7 or 2.1.1) are not provided to any Third Party for the purposes of any such study that has not been authorised by Liverco;

save that where Program IP is in or comes into the public domain (other than as a result of a breach of any obligation of confidentiality owed by UCLB, UCL or an Academic Collaborator), the provisions of this Clause 4 shall not apply in respect of Academic Research relating to such Program IP, except where the Academic Research is conducted by AN and/or the AN Laboratory in which case these provisions shall continue to apply.

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- 4.3 If UCL or any Academic Collaborator (which for the purposes of this Clause 4.3 shall include any of their respective academics, employees or students), wish to publish (including by way of publication of any thesis) (i) any of the Program IP; or (ii) with respect to each Improvement for the duration of the period prior to and during the applicable Improvement Negotiation Period, any results of Academic Research that amount to Improvements (each of (i) and (ii) being “**Academic Information**”) then UCLB shall procure that:
- 4.3.1 UCL and the Academic Collaborator shall refrain from making any publication (or submitting for approval any publication) of any of the information in the Academic Information (or the Academic Information in its entirety) pending conclusion of all steps required under this Clause 4.3;
 - 4.3.2 until the Additional Patent Rights have been published in accordance with the prosecution of such applications within that defined term, no publication, or request to publish under this Clause 4.3, shall be made with respect to any of the Additional Program IP or any results arising from use of any of the Additional Program IP, and following publication of the Additional Patent Rights in accordance with the prosecution of the applications within that defined term, then UCL may submit requests to publish under this Clause 4.3;
 - 4.3.3 subject to Clause 4.3.2, UCL or the Academic Collaborator(s) must first, via UCLB, give to Liverco, in advance, a copy of the proposed publication containing the Academic Information and which is intended to be disclosed or published, or submitted for publication at least [**] before its presentation or intended submission for publication (“**Academic Reports**”);
 - 4.3.4 upon receipt of the Academic Reports in accordance with Clause 4.3.3, Liverco shall within [**] of receipt either approve or (where Liverco has legitimate commercial concerns including wanting to seek patent protection of the relevant Academic Information or part thereof) refuse the request for publication, but failing UCLB’s receipt of Liverco’s notice within the [**] time period, the request for publication shall be deemed to be approved in the form in which the Academic Reports were provided to Liverco pursuant to Clause 4.3.2;
 - 4.3.5 where the request for publication is refused, the refusal shall be communicated to UCLB in writing, following which UCLB shall procure that UCL and the Academic Collaborator(s) shall refrain from making any publication of the Academic Reports (and the Academic Information contained in such Academic Reports) for a period no less than [**] (or no less than [**] if agreed by UCLB) from the date of notification from Liverco refusing the request for publication;
 - 4.3.6 if consent is given to the request for publication, or where refused the period of [**] (or such longer period as agreed) pursuant to Clause 4.3.5 has expired, UCL and/or the Academic Collaborator(s) may proceed to publish the Academic Reports in the form in which they were provided to Liverco pursuant to Clause 4.3.2;

- 4.3.7 save in respect of [**], Clauses 4.3.1 to 4.3.6 shall not prevent or hinder any student from submitting for degrees of UCL or any Academic Collaborator any thesis containing Academic Information or from following the procedures of UCL or any Academic Collaborator for examination and for admission to postgraduate degree status provided that such procedures require the thesis to be placed on restricted access within the library of UCL (and the Academic Collaborator, if applicable and acceptable under the relevant policies of the Academic Collaborator) for [**] of placement of the thesis at the library of UCL (and the Academic Collaborator, if applicable and acceptable under the relevant policies of the Academic Collaborator).
- 4.4 Where Liverco has exercised its right to refuse the request for publication of any Academic Reports, then Liverco and UCLB shall promptly and collaboratively work together in order to assess, and where appropriate, file and seek appropriate patent protection for the Academic Information. Where UCLB files for patent protection, the costs for seeking such protection shall be borne by UCLB.
- 4.5 UCL shall have the limited right to sub-license the Academic Rights (excluding those relating to Additional Program IP) through one tier only, to Academic Collaborators for named staff to work on with respect to a collaborative Academic Research project in conjunction with UCL (a **“Collaborative Research Project”**). Such sub-licence shall:
- 4.5.1 only be granted provided that all results and Intellectual Property arising from a Collaborative Research Project shall be subject to Liverco’s right to exercise its rights over those results and Intellectual Property which are Improvements in accordance with the provisions of Clause 5 and the Parties acknowledge that this obligation shall not apply in respect of results or Intellectual Property which are not Improvements;
 - 4.5.2 be in writing and the Intellectual Property licensed, and Materials provided, shall be limited for use solely by the named individuals at the Academic Collaborator and for that Collaborative Research Project only;
 - 4.5.3 be subject to all the conditions and restrictions set out in this Clause 4, which UCL and UCLB shall ensure are binding on such Academic Collaborator, with UCLB procuring compliance;
 - 4.5.4 automatically terminate on conclusion of the Collaborative Research Project, and require the return of any Materials provided by UCL (or its academics or laboratories) under or pursuant to the Collaborative Research Project;
 - 4.5.5 not permit, and positively restrict, the Academic Collaborator from undertaking any of the studies referred to in Clauses 4.2.4 and 4.2.5 without Liverco’s prior written consent; and,

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- 4.5.6 be promptly notified to Liverco, within [**] of grant of such sub-licence and, to the extent it is able to do so, provide Liverco with a copy of the agreement with respect to the Collaborative Research Project (with confidential and financial information redacted) promptly following its execution.
- 4.6 UCLB shall procure the compliance of any Academic Collaborator(s) with the provisions of this Clause 4 by including these terms in an agreement with the Academic Collaborator(s). UCLB shall be responsible to Liverco for any act or omission of a sub- licensee who is granted a sub-licence by UCL under Clause 4.5 where such act or omission if committed by UCL or UCLB would be a breach of this Agreement.
- 4.7 UCLB warrants and represents to Liverco that, with the exception of the [**] concerning the HLP1 Promoter Product, that the agreements disclosed to Liverco and identified in Part A of Schedule 6 comprise all licences, consents, waivers and/or permissions (whether express or implied) granted by UCL and/or UCLB in respect of any of the Program IP, UCL Background IP (that is subject to the exclusive licence pursuant to Clause 2.1.1) and Manufacturing Know-How (that is subject to the exclusive licence pursuant to Clause 2.2.1) to any Third Party (**“Existing licences”**). UCLB warrants and represents to Liverco that as of the Effective Date, the summary description in relation to the provisions of the [**] that govern the grant, use, field, restrictions, prosecution and enforcement of the patent application claiming the HLP1-Product and is set out in an email between [**] is accurate and complete in all material parts, and that such provisions are as of the Effective Date in force. Notwithstanding the foregoing, UCLB shall not be deemed in breach of the requirements or restrictions under this Clause 4 with respect to those Existing licences provided that such Existing licences shall not be amended after the Effective Date without the prior written consent of Liverco (not to be unreasonably withheld or delayed) nor shall their duration be extended or consent granted under them to allow materials to be provided to a Third Party.
- 4.8 Save for the limited right granted to UCL under Clause 4.1 to undertake Academic Research, UCLB shall retain no other rights that deviate from or otherwise encumber, limit or affect the licences (including their scope, termination and duration) granted to Liverco hereunder.
- 4.9 If UCL or any Academic Collaborator wish to publish (including by way of publication of any thesis) any results of Academic Research that amount to a New Invention for the duration of the period prior to and during the applicable Improvement Negotiation Period, the provisions of Clause 4.3 shall apply, save that Liverco shall have no more than [**] receipt of the proposed publication to either approve or request delay of the publication and Liverco shall only be entitled to delay publication for a maximum duration [**] [**] from receipt of the publication.
- 5. ACCESS TO IMPROVEMENTS AND NEW INVENTIONS**
- 5.1 The provisions of this Clause 5 shall apply to each and every Improvement and New Invention that is generated, reduced to practice or otherwise discovered or identified at any time up until and including the [**] of the Effective Date

(“Improvement Period”). UCLB shall procure that UCL, AN and the AN Laboratory shall comply with the terms of this Clause 5 and notify UCLB of all Improvements and New Inventions in order that UCLB shall be able to comply with this Clause 5.

5.2 From the Effective Date until expiry of the Improvement Period, UCLB shall notify Liverco of each and every Improvement and New Invention generated, developed or arising in such period within [**] of UCLB’s receipt of an invention disclosure form describing the Improvement or New Invention (in respect of each Improvement and each New Invention, each notification to Liverco being a **“Disclosure Notification”**). In respect of Improvements and New Inventions which UCLB is obliged to notify to Liverco:

- 5.2.1 UCLB shall procure the exclusive right (to the exclusion of UCL and the inventor(s)) to license, assign, exploit or otherwise grant any rights to that Improvement or New Invention (as applicable) to, any Third Party, and shall ensure that such Improvement or New Invention (as applicable) is kept confidential including by its Academic Collaborators (subject to the publications procedure under Clause 4.3 and 4.9) until Liverco ceases to have any rights (exercisable, negotiable or otherwise) to that Improvement or New Invention (as applicable) under the terms of this Clause 5;
- 5.2.2 UCLB shall procure that the Disclosure Notification shall provide (i) in good faith reasonable details of that Improvement or New Invention (as applicable) with a reasonable level of detail and information sufficient to enable Liverco the opportunity to fairly assess the opportunity to take a licence to and evaluate the Improvement or New Invention at its application; (li) responses to Liverco for additional information and clarification beyond the information provided under (i); and (iii) any draft or pending application for registered patent protection in respect of that Improvement or New Invention (as applicable); in each case disclosure to Liverco shall be subject to the confidentiality obligations of this Agreement;
- 5.2.3 UCLB shall procure that Liverco shall have reasonable access to those individuals at UCL that invented, generated, discovered or developed that Improvement or New Invention (as applicable) in order to allow a confidential discussion as to the nature and features of that Improvement or New Invention (as applicable) and its application;
- 5.2.4 UCLB shall not, until Liverco ceases to have any rights (exercisable, negotiable or otherwise) to that Improvement or New Invention (as applicable) under the terms of this Clause 5, encumber, charge, mortgage, license, self, assign, Exploit or otherwise grant any other right or enable any Third Party to Exploit the Improvement or New Invention (as applicable);

provided that Liverco acknowledges that New Inventions may be subject to the rights of Funders in accordance with Clause 4.2.1 and that Liverco’s ability to exercise its rights under this Clause 5 may be dependent on any such Funder providing its consent to the terms of Exploitation of the New Invention in question, which consent UCLB shall use reasonable endeavours to obtain.

- 5.3 Following the date of the Disclosure Notification, Liverco shall have the right, exercisable at any time up until expiry of the Improvement Negotiation Period {irrespective of whether that is before or after the Improvement Period) to exercise its right of first negotiation in respect of obtaining a worldwide, assignable, sub-licensable (through multiple tiers) licence within the Field of the applicable Improvement or New Invention that is the subject of the Disclosure Notification, such licence to be exclusive or non-exclusive, as agreed by the Parties.
- 5.4 Upon Liverco exercising its right of first negotiation in respect of an Improvement or a New Invention (as applicable) by way of serving a written notice on UCLB, the following shall apply until expiry of the applicable Improvement Negotiation Period for that Improvement or New Invention {as applicable), unless extended by agreement between the Parties:
- 5.4.1 unless the Parties agree to terminate negotiations during the Improvement Negotiation Period, Liverco and UCLB shall promptly and actively negotiate throughout the Improvement Negotiation Period, in good faith and acting reasonably, fair and reasonable terms for and a conclusive agreement upon which that Improvement or New Invention {as applicable) may be licensed to Liverco;
 - 5.4.2 in so far as UCLB fails to comply with the provisions of Clause 5.4.1, the Improvement Negotiation Period shall be extended by a period equal to, or otherwise fairly calculated to, compensate for any delay in or absence from a negotiation by UCLB in accordance with the principles under Clause 5.4.1;
 - 5.4.3 in its negotiations around the fair and reasonable financial and other terms for a licence of Improvements {as opposed to New Inventions), UCLB shall have regard to the existing licensing and financial structure under this Agreement with respect to the Royalty Product to which such Improvement relates or is applicable.
- 5.5 If Liverco, by written notice, elects in writing not to continue with negotiations over an Improvement or a New Invention, then without prejudice to the remainder of this Clause 5 or any other Improvements or New Inventions, the Parties shall be released from their then current obligations to negotiate in accordance with Clause 5.4 with respect to that particular Improvement or New Invention.
- 5.6 Subject to UCLB's compliance with Clause 5.4.1, if the Improvement Negotiation Period has expired with respect to an Improvement or New Invention (as applicable), and that Improvement or New Invention (as applicable) has not been licensed to Liverco, then:
- 5.6.1 in respect of that Improvement, subject to the terms of Clause 5.7, UCLB shall be entitled to (i) instigate negotiations with Third Parties for the grant of a licence of that Improvement; or (ii) engage in negotiations solicited by Third Parties to agree terms for the grant of a licence of that Improvement to that Third Party; or
 - 5.6.2 in respect of that New Invention, Liverco shall cease to have any further rights to negotiate or match terms for any licence of rights to that New Invention under this Clause 5, save that the foregoing shall be without prejudice to any other New Inventions.

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5.7 In negotiating with any Third Party to grant a licence of an Improvement to that Third Party, for a [**] after the expiry of the Improvement Negotiation Period (“**Match Period**”) or Liverco having served notice under Clause 5.5:

5.7.1 UCLB shall not accept or agree any term (or overall set or combination of terms) that are [**] to [**] and,

5.7.2 [**]

5.7.2.1 [**]

5.7.2.2 [**]

5.7.2.3 [**]

5.8 The provisions of Clause 5.7 shall apply each and every time that UCLB instigates in or engages in negotiations with any Third Party concerning an Improvement during the Match Period, such that if negotiations with a Third Party break down and either re-commence with that Third Party or new negotiations begin with a different Third Party to that Improvement, the provisions of Clause 5.7 shall continue to apply again.

Bi-specific technology.

5.9 If a program of research undertaken at UCL led by or under the primary supervision of AN:

5.9.1 requires for the reasonable commercial exploitation of the results of that program as a matter of necessity the right to use any methods or techniques that would, if performed by a Third Party, infringe any claim of the [**] Rights and there is no other reasonable way to exploit the results of such program without such use (an “[**] **Dependent Program**”); or,

5.9.2 is concerned with any antibody binder or derivatives thereof delivered by MV technology which has a bi-specific targeting mechanism of action (including where both binding moieties are identical) with any application outside of the Excluded Field but (a “**Bi-specific Program**”);

(collectively an “**AN Program**”) then UCL shall by written notice (an “**AN Program Notice**”) notify Liverco of such program upon the earlier of (i) UCL either approaching or being approached to license or sell any aspect of such AN Program (including any of the Intellectual Property Rights arising from it) for commercial exploitation; or, (ii) the publication of any patent application filed by, with the authority of or on behalf of AN, UCL or UCLB in respect of any invention derived from an AN Program; or, (iii) UCL having an offer (capable of acceptance and which UCL has a bona fide intention to accept) for a funding grant to undertake a formal toxicology study of, or to engage the clinical manufacturing of, a candidate product arising from an AN Program. This Clause 5.9 and Clause 5.10 shall apply each time to each and every AN Program as it arises.

5.10 Until such time as Liverco’s rights under Clause 5.9 and 5.10 expire (including any period of exclusive negotiation) with respect to an AN Program (and any of the Intellectual Property Rights arising from it), UCL shall not encumber, charge, mortgage, license, sell, assign, Exploit or otherwise grant any other right or enable any Third Party to Exploit such AN Program (including any of the Intellectual Property Rights arising from it). Each AN Program Notice shall include a reasonable disclosure of the applicable AN Program and the Intellectual Property Rights arising from it, and UCL shall through disclosures and/or meetings requested by Liverco afford Liverco a fair and reasonable opportunity to assess the benefit of the AN Program and the Intellectual Property Rights arising from it. Within [***] of such AN Program Notice or, if later, [***] following a meeting at which the AN Program and the Intellectual Property Rights arising from it is reasonably disclosed to Liverco so as to enable it to make a fair assessment of the same, Liverco shall notify UCL if it or an Affiliate of it wishes to negotiate for rights to the AN Program (including any of the Intellectual Property Rights arising from it). Where:

5.10.1 Liverco does not serve notice to negotiate for rights to the AN Program (or any of the Intellectual Property Rights arising from it) in accordance with the foregoing, then:

5.10.1.1 UCL shall be free to license or sell any aspect of such AN Program (including any of the Intellectual Property Rights arising from it) for commercial exploitation; and,

5.10.1.2 Where the AN Program Notice was in respect of a [***] Program UCL shall have the right, by serving notice on Liverco (within [***] of expiry of the deadline for Liverco to serve notice to negotiate for rights to the AN Program or its technology), to negotiate in good faith and acting reasonably for a licence to the [***] (or a variation to the scope of [***] to return rights) on commercial terms (to be agreed acting reasonably) to the extent necessary to exploit the results of such AN Program provided that (i) the AN Program is not applicable

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within the [**] and (ii) liverco is free and entitled, without breaching or offending any other rights granted or optioned by it as of the date of such notice, to license the [**] for such AN Program;

- 5.10.2 Liverco does serve notice to negotiate for rights to the AN Program (or any of the Intellectual Property Rights arising from it) in accordance with the foregoing, then UCL and Liverco will in good faith negotiate the commercial terms for and seek to conclude a licence to such AN Program and/or the Intellectual Property Rights arising from it as identified by liverco, for an exclusive period of no less than [**].

6. INFORMATION AND ACCESS TO PROF. AMIT NATHWANI'S OTHER PROGRAMS & OTHER RESTRICTIONS

- 6.1 During the Improvement Period, the Parties shall hold regular meetings to review the activities of AN (except in connection with his direction or supervision of the Haemostasis Group) and the AN Laboratory. Such meeting shall be held on an annual basis or sooner where (i) AN wishes to report a particular piece of research to Liverco and/or (ii) Liverco requests a meeting, subject to such liverco requests not exceeding three (3) in any year.

- 6.2 At each meeting UCLB shall update Liverco (under the confidentiality obligations of this Agreement) in respect of:

- 6.2.1 research activities being undertaken by AN and the AN Laboratory, together with progress and advances made under all research activities since the last meeting was held;
- 6.2.2 any change in status of AN's position at UCL (including termination of the same) or the AN Laboratory;
- 6.2.3 any collaboration with Academic Collaborators entered into by AN and/or the AN Laboratory; and,
- 6.2.4 any proposed applications for Patent Rights;

provided that the foregoing shall not require any disclosure of research activities being undertaken by AN and/or the AN Laboratory where UCL, AN and/or AN Laboratory are restricted from disclosing any such information as a result of obligations of confidentiality owed to a Third Party.

- 6.3 For any new inventions generated, reduced to practice or otherwise developed by or under the supervision of AN (whilst employed at UCL) and/or the AN Laboratory from time to time up until [**] and in respect of which Liverco does not have any rights pursuant to Clauses 5 (“**Other Technology**”), UCLB shall provide and procure that Liverco shall have a right of first review according to Clause 6.4. New inventions generated, reduced to practice or otherwise developed by the Haemostasis Group under the supervision of AN unless and until they become relevant for development of a therapy or therapeutic product shall not form part of other Technology.

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- 6.4 Where Other Technology is Controlled by UCLB or UCL and where UCLB or UCL makes any bona fide decision to seek a licensee to Exploit any Other Technology, or any bona fide approach is made by a Third Party to seek rights to or under any of the Other Technology which UCLB or UCL genuinely intends to engage in, UCLB shall not, and shall procure that UCL shall not, disclose the other Technology to any Third Party for the purposes of instigating or encouraging any licensing discussions nor offer to license the Other Technology to any Third Party, in each case prior to disclosing to Liverco at least [**] in advance (and in no less detail than it will disclose to any Third Party) the same other Technology.

Commercial Restrictions

- 6.5 The Parties acknowledge that the involvement of AN in Liverco is crucial and fundamental to Liverco's business. Accordingly, in recognition of the foregoing UCLB hereby agrees and undertakes that for a period of [**] the Effective Date, and with respect to any liver directed gene therapy using any viral vector other than in the Excluded Field, UCLB shall procure that for so long as AN is employed by or holds any position or undertakes or supervises any research at UCL during such period, that:
- 6.5.1 AN shall not undertake any Commercial Research himself or through the AN Laboratory;
 - 6.5.2 without Liverco's prior written consent, neither AN or UCL shall accept or use any funding to enable AN to undertake any Commercial Research himself or through the AN Laboratory; and
 - 6.5.3 without Liverco's prior written consent, AN shall not participate in, contribute to or otherwise supervise any Commercial Research;
- save that the foregoing shall not prevent AN from undertaking (i) that Commercial Research which is on-going as of the Effective Date in respect of which details have been disclosed to Liverco as outlined in Schedule 6, (ii) any Approved Activity (as such term is defined in the SSA); (iii) Commercial Research on behalf of Liverco; and (iv) Commercial Research (being limited to [**]) through the Haemostasis Group provided that it is not specifically directed to isolating, characterising and/or developing therapeutic products or therapies.
- 6.6 Should Liverco be sold (comprising the transfer of all shares in Liverco to a Third Party or the sale of all assets of the business of Liverco to a Third Party) and AN ceases to be employed or provide consultancy to Liverco (in the case of a share sale) or the Third Party acquirer (in the case of either a share sale or asset sale) then the restriction under Clause 6.5 shall terminate on the earlier of (i) [**] after the Effective Date; or (ii) [**] following the completion of the relevant sale.

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- 6.7 If UCLB wishes for one or more individuals working under the supervision of AN not to be considered to be members of the AN Laboratory (if, for example such individuals are visiting academics who are not employed by UCL and have no involvement in the Programs), UCLB shall notify Liverco of the names of such individuals, their proposed research and reasons why UCLB believes that such individuals should not be considered to be members of the AN Laboratory. Liverco shall within [**] of receiving the notification, and acting reasonably and in good faith, confirm to UCLB whether such individuals are deemed not to be members of the AN Laboratory. If Liverco fails to respond within [**] of receiving the notification from UCLB, the individuals in question shall, subject to Clause 6.8, be deemed not to be members of the AN Laboratory.
- 6.8 Where Liverco has in accordance to the provisions of Clause 6.7, confirmed to UCLB (or is deemed to have confirmed to UCLB) that one or more named individuals shall be deemed not to be members of the AN Laboratory, Liverco is entitled to revoke such confirmation (or deemed confirmation) by written notice to UCLB, provided Liverco has made such decision acting reasonably and in good faith.
- 6.9 Notwithstanding any restriction under this Clause 6, if Liverco elects not to develop and/or utilise a cell line capable of expressing recombinant [**] for humanitarian purposes to deliver recombinant [**] protein to developing countries, and AN wishes to do so, then AN shall have the right to work with a Third Party to develop and utilise such cell line provided that it is only used for delivering [**] protein to developing countries pursuant to a humanitarian purpose and policy and is done on a not-for-profit basis.

7. MATERIALS TRANSFER AND ENABLEMENT OF THE LICENSED RIGHTS

- 7.1 From the Effective Date and thereafter until the [**] anniversary of the Effective Date:
- 7.1.1 UCLB shall procure the disclosure to Liverco by UCL, AN and the AN Laboratory of all Technology licensed hereunder in accordance with the timeline and practical disclosure steps set out in Schedule 5.
- 7.1.2 after compliance with, or to the extent that disclosure has not been complete under Clause 7.1.1, in each case UCLB shall thereafter upon request and/or on its own accord, continue to disclose to Liverco, and procure the disclosure to Liverco by UCL, AN and the AN Laboratory, of any Technology not disclosed under Clause 7.1.1, and will also carry out further disclosure or procure further disclosure of the Technology by AN and/or the AN Laboratory promptly following Liverco's request from time to time (and in any event, not later than [**] following Liverco's request);
- 7.1.3 UCLB shall procure that each of UCL, AN and the AN Laboratory shall help facilitate any technology transfer or teach-in (including any demonstrations) concerning any of the Technology; and,

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- 7.1.4 it being understood that such disclosure should be in the English language and should be disclosed in a structured and helpful manner to enable the proper understanding, benefit and access to the technology in respect of each Program and the Program IP.
- 7.2 Where the Technology referred to in Clause 7.1 above comprises Materials, UCLB shall procure the delivery of a reasonable quantity of samples of such Materials and UCL shall itself be entitled to retain a reasonable quantity of the Materials for the exercise of its Academic Rights subject to and in accordance with the provisions of Clause 4.
- 7.3 Where any materials which are not Program Materials have been used in connection with any of the Programs but are not Controlled by UCLB and so do not fall within the definition of Background Materials, UCLB shall (i) identify such materials in writing to Liverco; and (ii) use its reasonable endeavours to obtain consent from the relevant Third Party(ies) which Controls such materials, for the transfer of such materials to Liverco (and for the licensing of associated Intellectual Property) or otherwise assist Liverco in obtaining access to and the right to use such materials. Where UCLB uses its commercially reasonable efforts to obtain such consent from the Third Party(ies), it shall not be obliged to make any payment to such Third Party(ies). In the event that payment is demanded by the relevant Third Party, UCLB shall notify Liverco of such demand and Liverco may, in its sole discretion, decide to make a payment to obtain consent. This Clause shall not apply in respect of materials that are “off the shelf”, such as reagents and other commercially available Third Party materials, save that UCLB shall identify any “off the shelf” materials that are material to any of the Programs.
- 7.4 UCL shall retain ownership and possession of all Laboratory Notebooks and UCLB shall procure throughout the Term:
- 7.4.1 physical access for Liverco (including the right for Liverco to physically borrow from UCL’s possession and copy), upon reasonable notice by Liverco, of any Laboratory Notebooks in so far as they concern any of the Programs, Program IP, UCL Background IP or Manufacturing Know-How;
- 7.4.2 that all Laboratory Notebooks shall be kept reasonably safe and secure and protected from loss, damage or destruction in accordance with standard UCL process; and,
- 7.4.3 that the Laboratory Notebooks shall not be destroyed without UCLB first offering the same to Liverco.
- 7.5 UCLB shall CO-Operate and collaborate with Liverco to provide, and procure, guidance, information and know-how from time to time from AN and AN Laboratory about Program IP and the Technology.
- 7.6 UCLB shall not, and shall procure that UCL (including AN and the AN Laboratory) shall not, transfer, lend, supply or otherwise provide (i) any Laboratory Notebooks to any Third Party and/or (ii) any Program Materials to any Third Party except in the exercise of UCL’s Academic Rights subject to and in accordance with the provisions of Clause 4 and provided that those same Program Materials have been provided hereunder to Liverco.

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7.7 UCLB shall procure that UCL (including AN and those engaged in the AN Laboratory) shall:

- 7.7.1 keep the Program IP (subject to any disclosure in accordance with patent prosecution of the Licensed Patents) and Manufacturing Know-How confidential, such that any disclosure of the same to any Third Party in the course of Academic Research in accordance with Clause 4 or in the exercise of rights retained by UCLB in respect of the Manufacturing Know-How shall be subject to appropriate legally binding obligations of confidentiality;
- 7.7.2 not disclose the Program IP to any Third Party, other than as expressly permitted in the course of Academic Research pursuant to Clause 4;
- 7.7.3 shall not enable or assist any Third Party to Exploit any of the Program IP other than as expressly permitted in the course of Academic Research pursuant to Clause 4; and,
- 7.7.4 shall not enable or assist any Third Party to Exploit any of the UCL Background IP or Manufacturing Know-How within the Exclusive Field other than as expressly permitted in the course of Academic Research pursuant to Clause 4.

8. OPTION TO ACQUIRE PROGRAM IP

8.1 At Liverco's sole option, liverco may serve notice on UCLB to exercise, on a Product-byProduct basis, its right to acquire ownership of the relevant category of Licensed Patents, on the following basis:

Liverco option to require assignment (each an "Assignment Option") is available upon the occurrence of each applicable circumstance ("Assignment Trigger"):

- [**]
- [**]
- [**]
- [**]
- [**]

Liverco's Assignment Option relates to the following Licensed Patents:

- [**]
- [**]
- [**]
- [**]
- [**]

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Liverco option to require assignment (each an "Assignment Option") is available upon the occurrence of each applicable circumstance ("Assignment Trigger"):

Liverco's Assignment Option relates to the following Licensed Patents:

[**]

[**]

[**]

[**]

[**]

[**]

Each of the foregoing Assignment Options is exercisable in writing each time the applicable Assignment Trigger occurs, and the exercise of one Assignment Option shall not extinguish the right to exercise the other Assignment Options.

- 8.2 Upon service of Liverco's written notice in accordance with Clause 8.1, UCLB shall, subject to the remainder of this Clause 8, cause (and do and procure all things necessary to affect) the assignment of the relevant Licensed Patents which are the subject of the Assignment Option to Liverco, including the execution of an assignment document in accordance with this Clause (the "Assignment"). Liverco accepts that such assignment document shall include a provision under which Liverco shall only be entitled to assign any such Licensed Patents if the acquirer of the relevant Licensed Patent enters into a written undertaking with UCLB confirming to UCLB that the acquirer, its Affiliates (or any sub-licensee of the acquirer or its Affiliates) shall pay UCLB Royalties for sale of the Royalty Products pursuant to the provisions of Clauses 11, 12 and 13 and that UCLB shall be entitled to undertake Royalty audits of the acquirer on the same basis as set out in Clauses 13.9 and 13.10. UCLB shall as of the date of assignment of the relevant Licensed Patents warrant to Liverco that the relevant Licensed Patents are assigned free of encumbrances and with full title guarantee and UCLB's liability with respect to such warranty shall be subject to the provisions of Clause 19.2.
- 8.3 The assignment of Licensed Patents pursuant to this Clause 8 shall not extinguish Liverco's obligation to pay Royalties for sales of Royalty Products or other financial commitments under Clauses 11, 12 and 13 and, upon any such assignment, the Parties shall amend this Agreement to the extent required to reflect such assignment. However, UCLB may request (but Liverco shall not be obliged to action) that Liverco considers a royalty buy-out upon such assignment.

9. DILIGENCE OBLIGATIONS

- 9.1 Subject to the remainder of this clause and compliance with Clause 2.6, Liverco shall use its commercially reasonable efforts to develop a Royalty Product one of each that is the subject of (i) [**]; (ii) [**]; (iii) the Fabry Licence; and [**]; in each case until such time as the applicable Licence is terminated. Additionally, where UCLB becomes entitled to exercise its right to

terminate the FIX Licence under clause 9.5 (following expiry of the relevant date) but UCLB does not exercise such right and its right to terminate expires, then Liverco shall, from that point in time and thereafter, use its commercially reasonable efforts to develop a Royalty Product that is the subject of the FIX Licence (until such time as the FIX Licence is terminated), it being acknowledged that failure by Liverco (or if applicable a Sub-Licensee) to have met the First Target Date or Second Target Date (or extended Second Target Date pursuant to Clause 9.3) shall not be deemed a breach of commercially reasonable efforts. No obligations under this clause 9.1 shall apply with respect to any FIX Product where UCLB did not have a right to terminate under clause 9.5 unless any of the circumstances in Clause 9.6 apply. With respect to Liverco's obligations to use commercially reasonable efforts, it is acknowledged that Liverco shall at its sole discretion have the right to determine the prioritisation of development of Royalty Products and not be obliged to develop a Royalty Product under each and every Program Licence at all times during the relevant period. It is recognised that in complying with the above, (i) Liverco shall have the right to determine in its sole discretion the prioritisation, on a purely commercial basis, of the various Royalty Products for development, and that Liverco's compliance with the foregoing shall be assessed on the basis of Liverco's entire product development portfolio including the Royalty Products; and (ii) the performance of Liverco's FIX Product in clinical trials will determine and influence the development of other Royalty Products, and (iii) until such time as a FIX Product has adequately advanced in clinical trials with robust data supporting a reasonable anticipation of that FIX Product achieving a Marketing Approval in Core Countries, Liverco is unlikely to have advanced the other Royalty Products.

- 9.2 Subject to clause 9.6, UCLB shall be entitled to terminate the FIX Licence if Liverco (or its Sub-Licensee) fails to [**] with respect to a FIX Product (such specific FIX Product being the **"First Iteration"**) and fails to notify UCLB accordingly in writing by [**] (**"First Target Date"**). Any termination by UCLB under this Clause 9.2 shall only be effective if UCLB provides written notice of termination to Liverco by no later than [**].
- 9.3 If Liverco (or its Sub-Licensee) anticipates that it will fail to meet the First Target Date and yet Liverco or its Sub-Licensee plans to continue development of the First Iteration, it shall notify UCLB no later than the First Target Date. UCLB may decide to waive its right to terminate the FIX Licence under Clause 9.2. in which case UCLB shall be entitled to extend the Second Target Date (as defined below) to cover the anticipated period of delay and if it is to do so, it must notify Liverco of a new Second Target Date within [**] of notice from Liverco under this Clause 9.3.
- 9.4 If Liverco or its Sub-Licensee decides to abandon development of the First Iteration it shall notify UCLB by the First Target Date. UCLB may decide to waive its right to terminate the FIX Licence under Clause 9.2 in which case the Parties hereby acknowledge that Liverco's obligations to develop a FIX Product that is not the First Iteration shall be subject to the diligence obligations set out in Clause 9.1.
- 9.5 Subject to clause 9.6, if Liverco (or its Sub-Licensee) fails to commence a [**] respect of the First Iteration (**"[**]"**) [**] (**"Second Target Date"**), or by the extended Second Target Date (as notified by

UCLB pursuant to Clause 9.3) and fails to notify UCLB no later than the Second Target Date (or extended Second Target Date if applicable) that Liverco (or its Sub-Licensee) will not meet the Second Target Date (or extended Second Target Date if applicable) in relation the First Iteration, UCLB may terminate the FIX Licence by providing written notice of termination to Liverco by no later than [**] or where applicable, terminate the FIX Licence no later than [**] after expiry of the extended Second Target Date. The Parties hereby acknowledge that Liverco shall not be obliged to adhere to or comply with the diligence obligations set out in Clause 9.1 in respect of any FIX Product until such time that: (i) the Second Target Date or extended Second Target Date (if applicable) has passed; and (ii) UCLB had the right to terminate the FIX Licence but elected not to exercise such termination right and accordingly ceases to have a right to exercise its termination right in respect of the FIX Licence under, and in accordance with, this Clause 9.5.

9.6 In the event that any of the following circumstances arise:

- 9.6.1 AN has ceased to be CSO (as such terms is defined in the SSA) of Liverco;
- 9.6.2 AN is (i) an employee of Liverco, but has served notice of resignation notice or (ii) a consultant to Liverco, but has served notice to terminate his consultancy;
- 9.6.3 AN is an employee or consultant of Liverco, but under a termination notice served by Liverco;
- 9.6.4 AN is subject to any [**] initiated by Liverco which has concluded with [**];
- 9.6.5 there have been unexpected regulatory hurdles in relation to the [**] that Liverco has or is required to overcome;
- 9.6.6 there has been unexpected and/or unfavourable clinical data arising from the [**] referred to in Clause 9.2;
- 9.6.7 there is a requirement by the Regulatory Authorities or ethics committee for Liverco or its Sub-Licensee to conduct additional clinical study(ies) before commencing the [**] using the First Iteration; and/or
- 9.6.8 there are ongoing, or have been, material difficulties in procuring satisfactory manufacturing and/or delivery of [**] including, without limitation, capacity availability, quality issues, yield issues, specification or stability issues,

the Parties agree that the provisions of Clauses 9.2 to 9.5 shall cease to apply and thereafter Liverco's diligence obligations set be limited to those in Clause 9.1 from such point onward. Should AN be subject to a [**] initiated by Liverco until such proceeding is finally concluded (or withdrawn) Liverco's diligence obligations under this Clause 9 and UCLB's right to terminate any licences under this Clause 9 shall be suspended, any time limits or deadlines on Liverco's diligence shall be automatically extended by the period of time commencing with written notice [**] that are the subject of [**] and ending upon the final determination of such procedure (or its withdraw).

- 9.7 It is acknowledged that Exploitation by Liverco's Affiliates and/or Sub-Licensees of any Royalty Product shall, for the purposes of this Clause 9, be considered activities of Liverco for assessing its use of commercially reasonable efforts under Clause 9.1, meeting the deadlines in Clauses 9.2 and 9.3 and otherwise the compliance with Clause 9.
- 9.8 With effect from [**] Liverco (and, in respect [**] after the provisions of both Clauses 9.2 and 9.3 cease to apply), thereafter by 31 March of each year, Liverco shall provide UCLB with a written report that will include a summary of its development timelines and major development steps in relation to the Royalty Products that were taken in the previous [**] and will include development timelines, budget and major development steps that Liverco anticipates shall be undertaken with respect to the Royalty Products for the following [**]. In addition to the foregoing, UCLB shall be entitled, if reasonable, to request details of FTE resource allocation and CRO costs incurred by Liverco. The foregoing obligation shall cease to apply with effect from the [**] of the Effective Date.
- 9.9 The parties acknowledge that the provisions of this Clause 9.9 shall only apply to the FIX Licence following UCLB having a right to terminate under Clause 9.5 and such right to terminate ceasing to have effect, following which the obligations in Clause 9.1 apply to the FIX Product. Without prejudice to the termination rights granted to UCLB under Clauses 9.2 and 9.5, non-compliance with this Clause 9 shall not result in a right to terminate this Agreement or any financial or equitable remedy (including any remedy in damages), but UCLB's sole remedy for non-compliance shall be limited to the right to terminate those specific Program Licences granted under this Agreement in accordance with Clause 9.10. It is acknowledged that notwithstanding any delay in development of one or more Royalty Products, a breach of this Clause 9 may be remedied by Liverco subsequently undertaking activities to commence development of the applicable Royalty Product following UCLB's written notice referred to below and as such a delay in development timeline is not an un-remediable breach. Prior to exercising any right of termination UCLB shall first be obliged to provide Liverco with a written notice setting out the basis for its allegation of breach by Liverco under this Clause 9, which notice shall set out the deficiencies by Liverco and set out a series of reasonable activities UCLB consider sufficient to remedy the breach. For the avoidance of doubt, UCLB's list of suggested activities shall not be a definitive or minimum list of what is required to remedy any breach. Upon Liverco's receipt of such notice, the Parties shall, promptly, in good faith and acting reasonably, (i) discuss ways for liverco to remedy or undertake activities in compliance with the obligations under this Clause 9 and (ii) agree a reasonable period of time within which Liverco will be required to undertake such activities. If the Parties fail to agree the period which Liverco has to undertake the activities, Liverco shall have [**] from the date Liverco or UCLB serves written notice stating in its view that an agreement under (li) cannot be reached to comply with its obligations under this Clause 9 for the Royalty Product(s) in respect of which the breach has occurred.

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- 9.10 Provided that Clause 9.9 has been complied with and the process set out therein followed, and provided that following [**] (or such other period agreed between the Parties) Liverco is still in breach of the same obligations under this Clause 9 in respect of the development of one or more Royalty Products that were the subject of the original breach notice under Clause 9.9, UCLB shall be entitled upon immediate written notice to terminate the Program Licence(s) granted, on a Program Licence by Program Licence basis, the Program Licence applicable to the Royalty Products where, in breach of its obligations hereunder in respect of such Royalty Products, Liverco has not met and has failed to remedy its diligence obligation under Clause 9.1 to develop such Royalty Products.
- 9.11 Upon termination of a Program Licence by UCLB pursuant to Clause 9.2, 9.5 or 9.10, UCLB shall have the option to negotiate with Liverco to agree terms for a licence to those applicable Liverco Improvements Controlled by Liverco which are free of restrictions and encumbrances and which specifically relate to the Product licensed under the Program Licence that has been terminated. The foregoing right of UCLB to negotiate with Liverco for the Liverco Improvements shall expire [**] following notice of termination served under Clause 9.8. This Clause 9.9 shall survive the termination of this Agreement [**] from the date of termination during which UCLB shall have a right to exercise its right under Clause 9.9.
- 9.12 Liverco shall, by written notice, promptly notify UCLB in the event that its Board takes any decision to permanently terminate development of Royalty Products under a particular Program Licence, whereupon Liverco shall have no further obligation to develop or Exploit any Royalty Product applicable to that Program Licence and the relevant Program Licence shall terminate as of the date of Liverco's written notice and the relevant provisions of Clause 22 shall apply.
- 10. UCLB MANAGEMENT FEE AND SHARES**
- 10.1 Liverco shall, during the Term of this Agreement, make a maximum of four (4) annual payments to UCLB each of GBP £30,000, with each annual payment being made within [**] of receipt of a VAT invoice addressed to Liverco, the first of which shall be issued no earlier than the first anniversary of the Effective Date, and thereafter for the remaining three (3) annual payments they shall be issued on each subsequent anniversary of the Effective Date.
- 10.2 In consideration of UCLB entering into this Agreement, Liverco shall issue and allocate to UCLB 4,000,000 Ordinary Shares (as such terms is defined in the SSA) in Liverco.
- 11. MILESTONE PAYMENTS**
- One-Off Success Milestone Payments
- 11.1 During the Term of this Agreement, upon the occurrence of any success milestone set out in the table below (each a "**Success Milestone**") Liverco shall, in accordance with Clause 13, pay to UCLB a sum equal to the amounts set against that Success Milestone in the table below (each amount being a "**Success Milestone Payment**").

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

<u>Success Milestone</u>	<u>Success Milestone Payment (GBP£)</u>
[**] and:	
[**]	[**]
[**] the [**]	[**]
[**] of [**] and:	
[**] the [**]	[**]
[**]	[**]
[**] and:	
[**]	[**]
[**]	[**]

11.2 The payment of Success Milestone Payments under Clause 11.1 above is subject to the following:

- 11.2.1 a Success Milestone Payment shall not be payable in respect of any Royalty Products which are launched as a therapeutic product following the launch of the [**] Product;
- 11.2.2 the aggregate maximum payment under this Clause 11 shall never exceed GBP £3,500,000;
- 11.2.3 only one Success Milestone Payment shall be payable per Success Milestone; and,

11.2.4 in calculating Net Sales for the applicable Royalty Product the currency exchange mechanism set out in this Agreement to calculate the relevant Net Sales shall be applied.

12. **ROYALTIES**

12.1 On a Program Licence-by-Program Licence basis, and in partial consideration of the grant of that particular Program Licence to Liverco, Liverco shall during the Royalty Term pay to UCLB a royalty on Net Sales of the applicable Royalty Product supplied by Liverco or its Sub-Licensees within the Territory, such royalty calculated as the percentage value of the Net Sales at the following rates subject to the terms and conditions of this Agreement, and in particular the remaining provisions of this Clause 12 (individually per Royalty Product a “Royalty” and collectively the “Royalties”):

	<u>Royalty Product and Field</u>	<u>Royalty Rate</u>
A	[**] a [**]	[**]
B	[**] the [**]	[**]
C	[**]	[**]
D	[**]	[**]
E	[**]	[**]
F	[**]	[**]

	Royalty Product and Field	Royalty Rate
G	[**] more of [**]	[**]
H	[**]	[**]
I	[**]	[**]
J	[**]	[**]
K	[**]	[**]
L	[**]	[**]

- 12.2 In partial consideration of the grant of the FX Vector Licence to Liverco, Liverco shall throughout the Royalty Term pay to UCLB a royalty on net sales of FX Vector Products supplied by Liverco or its Sub-Licensees within the Territory, such royalty calculated as [**] of the net sales of such FX Vector Products subject to the terms and conditions of this Agreement, and in particular the remaining provisions of this Clause 12. For the purpose of this Clause 12.2, the term “net sales” shall have the equivalent meaning to that in Part A of Schedule 8 wherein reference to Royalty Product shall mean FX Vector Product. The royalties due pursuant to this Clause 12.2 shall be included within the definition of “**Royalty**” and “**Royalties**”. Following expiry of the [**] referred to above, the FX Vector Licence shall become irrevocable, perpetual, royalty free and fully paid up.
- 12.3 Subject to Clause 12.5 and row E of the table above (which is an additive royalty in respect of the Serotype IP), only one Royalty Rate shall be payable per Royalty Product and the Royalty payable on a Royalty Product shall be calculated only once and payable only once. [**]
- 12.4 The Royalty and/or Royalty Rate in respect of a Royalty Product and the Royalty for a FX Vector Product set out above shall be adjusted, as applicable, in accordance with the provisions of Clause 12.5 to 12.10, and the order of reduction or adjustment in the Royalty Rate or Royalty due shall be applied sequentially in the order of those remaining clauses.

Multiple Royalty Product Adjustments

12.5 If any Royalty Product falls within more than one of the Royalty categories set out in the table at Clause 12.1, the maximum Royalty payable for that particular product or therapy shall be calculated as a percentage of the Net Sales for such Royalty Product at a rate being the sum of the highest Royalty Rate of all the Royalty Rates payable pursuant to Clause 12.1 for such Royalty Product, plus [**] of the next highest Royalty Rate of the remaining Royalty Rates payable pursuant to Clause 12.1 for such Royalty Product, save that if the second highest applicable Royalty Rate category for a product or therapy is category E, such Royalty Rate under category E shall not be discounted [**] per cent but shall be additive [**]. In respect of Additional Royalty Products however, notwithstanding the foregoing, only the one highest Royalty Rate shall apply. No Royalty pursuant to Clause 12.1 shall be due on any [**] Product.

Royalty Rate Reductions

12.6 In respect of each Royalty Product and on a country-by-country basis, the Royalty Rate applicable to the Net Sales for such Royalty Product shall be reduced by the percentages set out in the table below where the applicable circumstance exists or does not exist, as the context requires. Furthermore, where a product or therapy falls within two or more definitions of a Royalty Product, then the following circumstances shall be assessed on an individual Royalty Product-by-Royalty Product basis (and hence separate Royalty Rate by Royalty Rate basis) such that the Royalty Rate in respect of the product or therapy falling within one Royalty Product definition may be adjusted differently to the Royalty Rate that would be applicable for such same product or therapy also falling within a second definition for another Royalty Product.

<u>Circumstance in the country of sale in respect of the applicable Royalty Product</u>	<u>Percentage reduction to the Royalty Rate</u>
(a) [**]	[**]
(b) [**] (a) [**]	[**] (provided that the actual Royalty Rate under this circumstance shall not fall [**])

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Circumstance in the country of sale in respect of the applicable Royalty Product	Percentage reduction to the Royalty Rate
(c) [**]	[**] (provided that the actual Royalty Rate under this circumstance shall not fall below [**])
(d) [**]	[**]

12.7 For the purposes of Clause 12.6, the “**Know-How Period**” means the period of time commencing with the date that a Marketing Approval has been granted to Liverco or its Sub-Licensee within the USA or any country within the European Union (whichever is the first) for the relevant Royalty Product and [**] thereafter.

Royalty Stacking

12.8 If Liverco, its Affiliates or any Sub-Licensees in-license or acquire rights under or otherwise purchase (i) any Patent Rights from any Third Party (including an obligation from such Third Party not to assert the Patent Rights in question); and/or, (ii) subject to Clause 12.9 any Patent Rights from UCLB; and/or (iii) [**] (or part thereof), and such Patent Rights, [**] (as reasonably assessed, based on such Patent Rights [**] being reasonably required) to Exploit any Royalty Product(s) and/or [**] in any way (“**Third Party Access Rights**”), to the extent Liverco, its Affiliates or its Sub-Licensees are required to pay any consideration, royalties, monies, milestones, or other fees under or in connection with such Third Party Access Rights applicable to any Royalty Product(s) and/or [**] Product(s) (“**TP Fees**”), such TP Fees (which shall be calculated as at the full rate prior to applying any stacking or deduction provisions under the agreement applicable to the Third Party Access Rights) shall be deductible from Royalties otherwise due on those Royalty Product(s) and/or [**] Product(s) subject to a maximum deduction [**] that would otherwise be payable were it not for this Clause (“**Royalty Collar**”). The determination as to whether an acquisition, licence or non-assert amounts to Third Party Access Rights shall be determined by Liverco’s intellectual property counsel and if UCLB disagree with that determination (which it must do within [**] of notification by Liverco) then the matter shall be referred for final determination, binding on Liverco and UCLB, to an independent intellectual property lawyer with Liverco and UCLB each bearing [**] of the costs of such instruction and determination. If by virtue of the capsid gene sequence utilised in a Royalty Product and/or [**] Product, such Royalty Product and/or [**] Product infringes or would infringe (in the absence of a licence) any Capsid Claims of any Patent Rights filed (as opposed to claiming priority) [**] of the First Serotype Patent Rights identified in Part A of Schedule 2 (“**Vector Patents**”), then any TP Fees payable shall be deductible [**]

their value after deduction of all other TP Fees and the Royalty Collar shall not apply. For the purpose of the preceding sentence, “**Capsid Claim**” means any claim of a Patent Right that claims or covers any capsid having at [**] to the capsid sequences identified in Schedule 12 of this Agreement. Any dispute concerning whether the foregoing provision concerning any Vector Patents applies to any product, will be determined in accordance with the same procedure set out above to determine if Third Party Access Rights apply. For the avoidance of doubt, the Royalty Collar shall always apply, in all other circumstances.

- 12.9 If Liverco, its Affiliates or any Sub-Licensees in-license or acquire rights under any Patent Rights from UCLB that is (i) in the name of UCLB as of the Effective Date; and/or (ii) is filed by or on behalf of or at the direction of UCLB within [**] after the Effective Date in respect of any invention recorded in an invention disclosure form logged in UCLB’s database and categorised as “**Biopharm**” and with the status “being assessed” as of [**] to the Effective Date, then where such Patent Right is required to Exploit any Royalty Product(s) and/or [**] Product(s) in any way (as reasonably assessed, based on such rights blocking Exploitation), if Liverco, its Affiliates or any Sub-Licensees is required to pay any consideration, royalties, monies, milestones, or other fees under or in connection with such rights, the Royalty in respect of such Royalty Product(s) and/or [**] Product shall be reduced [**] For the avoidance of doubt, this Clause 12.9 shall not apply in respect of any sums paid by Liverco, its Affiliates or any Sub-Licensees in relation to the [**] where instead the provisions of Clause 12.8 shall apply.

HLP Promoter Licence

- 12.10 Where any product(s) triggers an HLP Royalty, and the same product(s) also triggers a Royalty under this Agreement, then the total value of Royalties due and payable hereunder for a particular Calendar Quarter shall be reduced [**] for such product(s) in same Calendar Quarter.

Diminished Royalty Product

- 12.11 If a Third Party (that is not authorised as a Sub-Licensee to Exploit a particular Royalty Product) commences Exploitation of any Competitive Product in a country within the Territory that infringes or otherwise misuses any of the Intellectual Property licensed hereunder (each an “**Competing Entrant**”), and UCLB and/or Liverco commence litigation against such Competing Entrant in respect of such Competitive Product, then in so far as any Royalties are due for sales of Royalty Product(s) in the country where litigation is ongoing and in respect of which the Competitive Product is competitive, such Royalties will be paid into escrow by Liverco pending resolution of such litigation. [**]

- 12.12 All interest earned on the sums paid into escrow pursuant to Clause 12.11 shall accrue to the benefit of the escrow account for distribution in accordance with Clause 12.11.

Royalty Term

- 12.13 The Royalty Term shall (i) in the case of Royalty Products commence on the Effective Date and shall, on a country-by-country basis and Royalty Product-by-Royalty Product basis, expire automatically upon there being a Royalty Expiry in a country in respect of a Royalty Product whereupon the rights and licences granted under this Agreement to Liverco in respect of such Royalty Product in such country (including any sub-licences granted by Liverco in respect thereof) shall become irrevocable, perpetual, royalty free and fully paid up; and, (ii) in the case of [**] Products commence on the Effective Date for shall expire automatically seven (7) years thereafter.

13. **REPORTING AND PAYMENT PROVISIONS**

Payment Provisions for Milestone Payments

- 13.1 Milestone Payments shall all be made in accordance with the following procedure:
- 13.1.1 Liverco shall, within [**] of the occurrence of a Milestone notify UCLB of such occurrence and its notification shall include the information listed in Schedule 10 in so far as relevant to the calculation of the Milestone Payment;
- 13.1.2 UCLB shall send to Liverco a VAT invoice addressed to Liverco in respect of the applicable payment due under Clause 11;
- 13.1.3 Liverco shall pay such invoice within [**] of the date of receipt of the same by Liverco.

Payment Provisions for Royalties

- 13.2 With effect from the First Commercial Sale of the first Royalty Product and/or [**] Product to be sold and throughout the remainder of the applicable Royalty Term, Liverco shall provide UCLB with a written report showing the gross selling price of those Royalty Products and/or [**] Product sold by Liverco and its Sub-Licensees in the preceding Quarter together with the calculations of Net Sales (as applicable to Royalty Products and [**] Product), which report shall include the information listed in Schedule 10 to the extent relevant to the calculation of Net Sales.
- 13.3 Quarterly reports shall be due within [**] of the close of every Quarter. Liverco shall keep accurate records in sufficient detail to enable the Royalties payable hereunder to be determined.
- 13.4 After receipt of the Quarterly report referred to in Clause 13.3, UCLB shall send to Liverco a VAT invoice addressed to Liverco in respect of the applicable payment due under Clause 12 as indicated in the royalty report.

- 13.5 Royalties shall be due and payable within [**] of the date such invoice is received by Liverco in accordance with Clause 13.4. Payments of Royalties due in whole or in part may be made in advance of such due date.

Late Payments

- 13.6 Any payment of any amount under this Agreement not received on the due date specified in accordance with this Clause 13 shall accrue interest thereafter on the sum due and owing from the date payment is due until the date payment is received at an annual interest rate equal to [**] over the base rate of the Bank of England in force from time to time.

Currency Conversion

- 13.7 All amounts payable pursuant to this Agreement shall be payable in Pounds Sterling by bank transfer to a bank account designated from time to time in writing by UCLB. In calculating Net Sales and Royalties under this Agreement, where receipts are received in a currency other than Pounds Sterling, such sums shall be calculated as Pounds sterling by converting such sums according to the spot rate for the Pound Sterling against the applicable currency as of midday on the day at the end of the applicable calendar Quarter, as such rate is advertised by the Financial Times in London.

Withholding

- 13.8 All amounts due under the Agreement shall be made after deduction of any withholding taxes, charges or other duties in the country of payment. Where any amount due to be paid under this Agreement is subject to any withholding or similar other tax, the Parties shall take reasonable steps to do such reasonable acts and things and sign such deeds and documents as reasonably appropriate to assist them to take advantage of any applicable double taxation agreements or other legislative provisions to reduce the rate of withholding or similar taxes with the object of paying the sums due under deduction of a reduced rate of withholding tax or on a gross basis. In the event there is no double taxation agreement or other legislative provision or the reduced rate of withholding tax under the relevant double taxation agreement is greater than zero per cent., Liverco (or its agent) shall promptly pay such withholding or similar tax by deducting the relevant amount from the payment due to UCLB, and send to UCLB proof of such withholding or similar tax in a form in accordance with the relevant taxation authority as evidence of such payments. Similarly, in so far as withholding or similar taxes are payable on sums ultimately due hereunder but are required to be made by Liverco's Affiliates or Sub-Licensees, such withholding may be made and Liverco shall work with UCLB to obtain from Liverco's Affiliates and Sub-Licensees proof that such withholding has been properly accounted for to the relevant tax authority and such documents as are reasonably necessary to allow UCLB to take advantage of any double taxation agreement, other legislative provision or reduced rate as may be available to it.

Royalty Audits

- 13.9 UCLB shall have the right to appoint, [**] on at least [**] prior written notice to Liverco, an independent certificated accountant reasonably acceptable to

Liverco to undertake an audit of Liverco's accounts and records relevant to the sales of Royalty Products and/or [**] Products and Net Sales to verify the accuracy of any payments due in respect of Royalties. UCLB shall ensure that any audit conducted pursuant to the HLP Promoter Licence shall be conducted at the same time as an audit under this Agreement, and *vice versa*, such that no more than one audit per [**] is conducted by UCLB under this Agreement and the HLP Promoter Licence. The independent certified accountant shall spend no more [**] at the premises of Liverco for the purpose of undertaking the audit. Thereafter, Liverco shall within [**] of receiving a written request from the independent accountant provide any additional information that is reasonable and reasonably requested for the purpose of assisting with the audit, provided that the foregoing obligation shall expire [**] after the audit. The independent auditor shall be required to enter into a confidentiality agreement on reasonable and standard terms with Liverco and shall not be entitled to disclose any confidential information of Liverco from the audit but shall be able to disclose whether or not Liverco is in compliance with its reporting obligations and the levels of Royalty declared and paid, and any discrepancy in the amount of Royalties declared as against those calculated to be due. To comply with its obligations under this Clause 13.9, Liverco shall include obligations in its sublicenses to obtain and make available to the auditor appropriate information from Sub-Licensees to enable the independent auditor to verify the accuracy of Royalties.

- 13.10 If, as a result of an audit being undertaken, any additional amount is found to be owed by Liverco to UCLB, such additional amount shall be paid within [**] after receipt of the accountant's report, along with interest at the annual interest rate [**] over the Bank of England base rate from the date that such additional amount should have first been paid until paid in full. If the amount underreported as Royalties for the relevant periods that are the subject of the audit, are in excess [**] in the relevant audit, then Liverco shall in full and final settlement of any claim of breach reimburse UCLB for those reasonable and customary costs charged by the independent auditor for conducting such audit (upon production of accompanying receipted invoices in respect of the same). If the accountant determines that there has been an overpayment by Liverco, the amount of such overpayment shall be refunded to Liverco within [**] after receipt of the accountant's report, or at Liverco's discretion, set-off against a future payment of Royalties or Milestone Payments.

Fair Market Value

- 13.11 Any disagreement between the Parties as to the fair market value for the purpose of calculating any Net Sales pursuant to Part A of Schedule 8 of this Agreement shall be referred to an expert for resolution in accordance with the provisions of Part B of Schedule 8. The value of such Net Sales in dispute shall (i) not be included in the calculation of the percentage of underreported royalties referred to in Clause 13.10 for the purposes of determining responsibility for the auditor's fees; and (ii) be excluded from any late payment charges or allegations of breach for non-payment until such time as the dispute is resolved, a value attributed and at least [**] has passed from such final determination. Notwithstanding the foregoing provision, if the expert determines that the fair market value is such that UCLB is entitled to additional sums, UCLB shall be

entitled to charge interest on any outstanding amount on a daily basis at a rate equivalent of [**] over the base rate of the Bank of England in force, such interest shall be payable from the date UCLB issues a notice disputing the fair market value until the date the UCLB receives such additional payment.

14. **BUY-OUT OPTION**

- 14.1 On a Royalty Product by Royalty Product basis, once the aggregate Net Sales for a Royalty Product have exceeded [**] Liverco shall thereafter have a right, exercisable on written notice at any time, to negotiate with UCLB to buy out UCLB's rights to Royalties and (if applicable) Milestone Payments on such Royalty Product (for each Royalty Product a **"Buy-Out Option"**). The reference to "buy out" in this Clause shall mean that UCLB shall cease to be entitled to Royalties or Milestone Payments in exchange for some other cash consideration.
- 14.2 Upon exercising the Buy-Out Option by way of Liverco serving a written notice on UCLB, the following shall apply until expiry [**] after the date Liverco's notice is deemed served (unless extended by agreement between the Parties):
- 14.2.1 Liverco and UCLB shall promptly and actively negotiate throughout the [**] in good faith and acting reasonably, fair and reasonable terms for, and the, conclusive agreement upon which the buy-out may be exercised;
- 14.2.2 in so far as UCLB does not actively and properly participate in such negotiations or does not act reasonably or in good faith, an independent expert shall be appointed by Liverco following the [**] determine the valuation of the buy-out on applicable industry standards.

15. **INTELLECTUAL PROPERTY PROSECUTION AND MAINTENANCE**

Ownership

- 15.1 Nothing in this Agreement shall assign or purport to assign any Intellectual Property rights owned by one Party to the other Party.
- 15.2 Subject to Liverco's right to exercise its option to acquire certain of the Program IP, UCLB is and shall at all other times remain the sole and exclusive owner of all right, title and interest in and to any and all Program IP and [**] IP. UCLB shall not assign, mortgage, encumber or otherwise gift or provide an option over any of the Licensed Patents or Program IP or [**] without the prior written consent of Liverco.
- 15.3 Liverco is and shall at all times remain the sole and exclusive owner of all right, title and interest in and to any and all Intellectual Property that it owns or Controls (other than by virtue of the licences granted hereunder) as of or after the Effective Date.

Patent Prosecution

- 15.4 In respect of the Licensed Patents:
- 15.4.1 UCLB shall not Surrender any of them without the prior written consent of Liverco;
- 15.4.2 from the Effective Date and during the Term for so long as Liverco holds a licence to the same, subject to Clause 15.5 Liverco shall at its expense have the exclusive control and conduct of all on-going prosecution and maintenance steps in respect of the Licensed Patents (the “**Responsible Patents**”);
- 15.4.3 UCLB shall provide all reasonable or appropriate assistance and cooperation required by Liverco to enable Liverco to efficiently and effectively discharge the prosecution and maintenance of the Responsible Patents and in doing so, UCLB shall follow all directions and instructions of Liverco and do all things reasonably required by Liverco with respect to the Responsible Patents;
- 15.4.4 UCLB shall ensure that all documents and correspondence that it, or its agents or other licensees receive in connection with any of the Licensed Patents shall be promptly and in any event within [**] forwarded to Liverco;
- 15.4.5 UCLB shall instruct those professional advisors, patent agents and lawyers who act on behalf of UCLB in the prosecution of the Responsible Patents to cooperate with Liverco, accept instructions from Liverco as if they were direct from UCLB and provide all history on the prosecution of the Responsible Patents to Liverco;
- 15.4.6 Liverco shall be entitled, at its discretion and cost, to appoint alternative counsel to take over the prosecution of the Responsible Patents;
- 15.4.7 UCLB shall promptly notify Liverco of any threatened or actual claim of invalidity or revocation or opposition of any of the Licensed Patents and shall provide full details and all such information available to it regarding such threatened or actual claim. Liverco shall have the right (but not obligation) to control, direct any actions for invalidity, revocation or oppositions issued against the Responsible Patents. UCLB shall do (or not do) all such things as are reasonably directed by Liverco to enable Liverco to control, direct and conduct such proceedings, including allowing Liverco’s legal representatives to conduct such proceedings in UCLB’s name where required or beneficial provided that Liverco indemnifies UCLB and/or its Affiliates for any Third Party costs, damages, expenses or liability incurred by UCLB and/or its Affiliates as a direct result of UCLB and/or its Affiliates assisting Liverco to conduct such proceedings subject to Clause 15.11. Liverco shall pay UCLB for any reasonable (economy) travel and reasonable subsistence costs incurred by UCLB and/or its Affiliates as a result of assisting Liverco under this Clause 15.4.7;
- 15.4.8 UCLB shall provide assistance to and co-operate with Liverco in accordance with this Clause 15 without any further cost to Liverco, save that (i) if UCLB personnel

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are required to participate in any opposition proceeding (or comparable proceeding before patent offices and courts) which requires full time involvement for more than [**] per annum per Program IP under any Program Licence, then for such excess co-operation beyond the [**] for that Program IP Liverco shall reimburse UCLB its reasonable costs, and (ii) this provision shall be without prejudice to the indemnity given in Clause 15.4.7; and,

15.4.9 any enforcement of the Licensed Patents shall be subject to Clause 16.

15.5 In respect of the Responsible Patents, Liverco shall:

15.5.1 subject to UCLB's compliance with Clause 15.4, be responsible for the Patent Prosecution Costs for the Responsible Patents;

15.5.2 keep UCLB informed of developments in the preparation, filing, prosecution and maintenance of the Responsible Patents and shall provide UCLB with copies of all material correspondence to and from its patent attorneys or patent offices in relation to the Responsible Patents and shall provide UCLB reasonable notice of and the opportunity at its own cost to participate in any conference calls or meetings with Liverco's patent attorneys in relation to the drafting, filing, prosecution and maintenance of the Responsible Patents;

15.5.3 consult with UCLB in connection with Liverco's strategy for the prosecution and maintenance of the Responsible Patents;

15.5.4 take into account any reasonable comments and suggestions of UCLB in relation to the prosecution and maintenance of the Responsible Patents; and

15.5.5 notify UCLB in advance of any steps Liverco proposes be taken which would change the specification or reduce the scope of the claims of any Responsible Patent, and having done so shall take into account any reasonable comments and suggestions promptly proposed by UCLB in relation to such steps.

15.6 Liverco and UCLB shall, promptly after the Effective Date, and thereafter throughout the Term appoint a designated and named member of its respective personnel, experienced in and responsible for Intellectual Property matters, which person shall act as the liaison between Liverco and UCLB (and UCLB's other licensees as necessary) with respect to the Licensed Patents and obligations thereto under this Agreement and shall make themselves available at reasonable times and on reasonable notice to address any matters concerning the Licensed Patents.

Validation and Maintenance

15.7 Liverco shall have the sole discretion to determine, on a reasonable basis and following its notification to UCLB, in which countries to maintain or Surrender the Responsible

Patents. Notwithstanding the foregoing discretion, if Liverco wishes to Surrender any of the Responsible Patents in any of the Core Countries then the following shall apply:

- 15.7.1 prior to taking any steps to Surrender a Responsible Patent in a Core Country, Liverco shall first provide UCLB with at least [**] notice of its intention identifying the Responsible Patent and applicable Core Countries;
- 15.7.2 UCLB shall have a right of step-in (to be exercised within [**] of notice from Liverco under Clause 15.7.1) to take over such Responsible Patent in the applicable Core Country and if it exercises such right (i) UCLB shall thereafter be responsible for all costs and expenses associated with such Responsible Patent for that applicable Core Country; (ii) Liverco's licence to that Responsible Patent for that applicable Core Country shall terminate; and (iii) UCLB and its licensees shall only have the right to undertake acts that would otherwise infringe that Responsible Patent in the applicable Core Country and shall ensure that any products manufactured in that Core Country under such Responsible Patent shall not be sold outside of that Core Country to the extent such restriction is permitted hereunder by law; and,
- 15.7.3 if UCLB does not exercise its step-in right in accordance with Clause 15.7.2, then Liverco shall be entitled without breach of this Agreement to Surrender such Responsible Patent in such Core Countries.

SPCs, Patent Notifications and Unitary Patent

- 15.8 Without the prior written consent of Liverco, UCLB shall not file any supplementary protection certificate or patent term extension right ("SPC") under any Licensed Patents with respect to the issue of any Regulatory Approval (including any Marketing Approval) for any product. Upon Liverco's request, UCLB shall file and, at Liverco's direction, control and expense, prosecute an application for an SPC against any of the Licensed Patents with respect to any product.
- 15.9 Where any country in the Territory requires the holder of a Regulatory Approval with respect to a biological medicinal product to designate one or more Patent Rights as being Patent Rights that protect such medicinal product (including the purple book listing required by the FDA) (an "**Purple Book Reference**"), then Liverco shall have the sole right to specify which (if any) Patent Rights should be listed in such references and UCLB shall list any of the Licensed Patents if Liverco wishes to do so.
- 15.10 In respect of the Responsible Patents, Liverco shall have sole discretion to determine whether to opt in or opt out (and to opt in again) of the Unified Patent Court system and UCLB shall promptly do all things necessary and execute all documents required to give effect to such decision(s).

Indemnity Conditions

- 15.11 Liverco's obligation to continue to indemnify UCLB pursuant to Clauses 15.4.7 and 16.2.2.2 is conditional upon:
 - 15.11.1 UCLB taking those steps, doing those things or refraining from doing those things requested of it by Liverco for the duration of the indemnification;

- 15.11.2 UCLB not making any admission or settlement (or taking steps to do so) concerning the proceedings without the prior written consent of Liverco;
- 15.11.3 Liverco having sole conduct of the applicable proceedings for the duration of the indemnification;
- 15.11.4 any damages, account of profits, financial remedy or costs recovered from Third Parties (whether in UCLB's name or otherwise) in respect of the applicable proceedings being for the sole account of Liverco.

16. **INTELLECTUAL PROPERTY ENFORCEMENT**

- 16.1 A Party shall notify the other of any information it has regarding any Third Party infringement of the Intellectual Property licensed under or pursuant to this Agreement in so far as such infringements are related to any products, services or processes.
- 16.2 In respect of any alleged, threatened or actual infringement of the Intellectual Property licensed or sub-licensed hereunder, but excluding the Promoter Patent Rights ("**Enforcement Action**") the following, shall apply:
 - 16.2.1 Liverco shall have the first right to determine whether or not it wishes to bring proceedings for the Enforcement Action and only if Liverco elects not to bring proceedings itself shall UCLB have the right to decide whether or not to bring proceedings for the Enforcement Action (but in doing so UCLB shall have regard to the advice and recommendations of Liverco);
 - 16.2.2 where Liverco, in exercising its right under Clause 16.2.1, decides to enforce any of the licensed Patents or other Intellectual Property licensed hereunder, then:
 - 16.2.2.1 at Liverco's expense, Liverco shall have the right to control, direct and conduct such proceedings;
 - 16.2.2.2 UCLB shall allow Liverco's legal representatives to conduct any litigation in UCLB's name (i) where required by law in the country of the Enforcement Action or (ii) to the extent beneficial to the enforcement or relief sought; and (iii) in doing so UCLB shall do (or not do) all such things as are directed by Liverco to enable Liverco to control, direct and conduct such proceedings provided that Liverco indemnifies UCLB and/or its Affiliates for any Third Party costs, damages, expenses or liability incurred by UCLB and/or its Affiliates directly as a result of assisting Liverco control, direct and conduct such proceedings subject to Clause 15.11 (it being acknowledged that UCLB shall have the right to be separately advised (but not represented before the proceedings) by its own counsel at UCLB's own expense). Liverco shall pay UCLB's and/or its Affiliates' costs for any reasonable (economy) travel and reasonable subsistence costs incurred by UCLB and/or its Affiliates as a result of assisting Liverco under this Clause 16.2.2.2;

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- 16.2.2.3 UCLB shall use its reasonable endeavours to procure that UCL and AN shall do all such things as are reasonably directed by Liverco to assist or enable Liverco to control, direct and conduct such proceedings;
 - 16.2.2.4 Liverco shall have the right to nominate, change or amend any Purple Book Reference and UCLB shall co-operate in such nomination, change or amendment to list any of the Licensed Patents if Liverco wishes to do so; and,
 - 16.2.2.5 Liverco shall keep UCLB promptly and fully informed of any and all steps and events in any proceedings (including promptly responding to any requests for information and allowing UCLB to attend any meetings) and shall give due consideration to any reasonable comments and suggestions of UCLB with respect to such Enforcement Action;
- 16.2.3 UCLB shall keep Liverco promptly and fully informed of any and all steps and events in any proceedings (including promptly responding to any requests for information and allowing Liverco to attend any meetings) which are not being directed or controlled by Liverco relating to any of the Licensed Patents or other Intellectual Property licensed hereunder and shall give due consideration to any reasonable comments and suggestions of Liverco with respect to such action;
- 16.2.4 any recovery of damages or other financial remedy obtained in respect of the Enforcement Action shall, after deduction of all litigation costs (comprising attorney fees, expert fees, taxes, charges, disbursements, court fees and other costs incurred in connection with proceedings), be (i) in the case of an Enforcement Action in respect of a Competitive Product, after a bone fide reduction to reduce the award to exclude any aspect of such award being made for punitive or triple damages, be treated as Net Sales, and (ii) in all other cases, including any portion of the award being made for punitive or triple damages, be for the account of Liverco; and,
- 16.2.5 any defence of the validity of the licensed Patents, where validity is put in issue after commencement of proceedings for the Enforcement Action shall, notwithstanding the provisions of Clause 15, be subject to this Clause 16.

17. CONFIDENTIALITY

- 17.1 The Parties acknowledge that in connection with this Agreement, either Party may disclose or may have disclosed itself or on its behalf (a “**Disclosing Party**”) to the other Party (each a “**Recipient Party**”) information belonging to such Party which information is marked or stated in writing to be “confidential” or “trade secret” information or where the circumstances of the disclosure and/or the nature of the information otherwise reasonably give notice of the confidential character of the information (“**Confidential Information**”). All such Confidential Information of a Disclosing Party shall, subject to Clause 17.3, be maintained in confidence by each Recipient Party and shall not be used

by the Recipient Party for any purpose except for its proper execution of its obligations under this Agreement and the Exploitation of any product or as otherwise expressly authorised (including, in respect of any confidential Know-How to the extent such Know-How is licensed to the Receiving Party) under this Agreement or to the extent otherwise agreed in writing by the Disclosing Party provided that the Recipient Party may disclose any Confidential Information disclosed to it by the Disclosing Party to the extent that such disclosure by the Recipient Party is:

- 17.1.1 to its employees, directors, consultants or sub-contractors but only on a “need to know” basis provided each such employee, director, consultant or sub-contractor is subject to obligations of confidentiality consistent with the obligations of confidentiality in this Clause 17;
- 17.1.2 to its sub-licensees in respect of confidential Know-How that is licensed to the Recipient Party, but only on a “need to know” basis provided each such sub-licensee is subject to obligations of confidentiality consistent with the obligations of confidentiality in this Clause 17;
- 17.1.3 to an Ethics Committee or Regulatory Authority in connection with any Ethics Committee Application or seeking or maintaining any Regulatory Approval for any product or therapy in accordance with this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such Information;
- 17.1.4 on a “need to know” and confidential basis to its, or its Affiliates’, legal and financial advisors to the extent such disclosure is reasonably necessary in connection with such Party’s activities as expressly permitted by this Agreement or for the conduct of its, or such Affiliates’, business;
- 17.1.5 to a prospective acquirer or licensee and such Third Party’s employees, advisors and representatives in each case on a “need to know” confidential basis for the sole purpose of considering such transaction provided that such persons are under substantially similar obligations of confidentiality and non-use as the Recipient Party is pursuant to this Clause 17.

- 17.2 Throughout the Term of this Agreement and thereafter, each Recipient Party shall exercise a reasonable degree of care being at least the same degree of care as it uses to protect its own Confidential Information of similar nature to preserve the confidentiality of all Confidential Information of the Disclosing Party. Each Recipient Party shall safeguard Confidential Information against disclosure to third parties, including Affiliates, employees and persons working or consulting for such Party that do not have an established current need to know such Confidential Information for purposes in connection with this Agreement or to whom the Recipient Party is not entitled to disclose the same pursuant to this Clause 17.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 17.3 The obligation of confidentiality contained in this Clause 17 shall not apply to any part of any Confidential Information of the Disclosing Party:
- 17.3.1 that was in the possession of the Recipient Party, without any restriction on use or disclosure, prior to receipt from the Disclosing Party;
 - 17.3.2 that was at the time of disclosure by or on behalf of the Disclosing Party, in the public domain by public use, publication or general knowledge;
 - 17.3.3 that became general or public knowledge through no fault of a Recipient Party following disclosure hereunder;
 - 17.3.4 that was properly obtained, without confidentiality or non-use restrictions, by the Recipient Party from a Third Party who was not under a confidentiality or non-use obligation to the Disclosing Party;
 - 17.3.5 that was documented to have been independently developed by or on behalf of the Recipient Party without the assistance of the Confidential Information of the Disclosing Party.
- 17.4 The foregoing obligations of confidentiality and non-use shall not be breached by a Recipient Party disclosing Confidential Information of the Disclosing Party to the extent the same is required to be disclosed by order of any court, governmental authority, Regulatory Authority or other regulatory body (including any listing authority or financial regulator) provided, however, that the Recipient Party should give the Disclosing Party prior notice of any such disclosure so as to afford the Disclosing Party a reasonable opportunity to seek, at the expense of the Disclosing Party such protective orders or other relief as may be available in the circumstances.
- 17.5 Except for any press release agreed by the Parties, neither party shall during the Term, disclose any financial terms of this Agreement without the prior written consent of the other Party except for such disclosure as may be reasonably necessary to either Party's bankers, investors, attorneys or other professional advisors or in connection with any actual or proposed merger, sale or acquisition or as may be required by law in the offering of securities or in securities or regulatory filings or otherwise.
- 17.6 The Parties acknowledge that confidential information may have been disclosed pursuant to the CDA to employees, partners and representatives of [**] who themselves may provide services or advice to or sit on the board of Liverco. UCLB hereby agrees that notwithstanding the terms of the CDA employees, partners and representatives of [**] who received confidential information from UCLB under the CDA shall be entitled to disclose the same to Liverco and its employees, directors, consultants or sub-contractors subject to the terms of this Clause 17.
18. **WARRANTIES AND COVENANTS**
- 18.1 Liverco and UCLB each respectively represent and warrant to the other that each of the warranties at Part A of Schedule 9 in respect of itself, its Affiliates, its assets, its knowledge or its Intellectual Property is accurate as at the date of this Agreement.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 18.2 UCLB represents and warrants to Liverco that (i) except as disclosed in a Disclosure Letter dated as of the Effective Date, each of the warranties at (i) Part B of Schedule 9 is accurate at the Effective Date; and (ii) each of the warranties at Part C of Schedule 9 is accurate at the Amendment Date.
- 18.3 For warranties given by UCLB in respect of its knowledge or awareness, such knowledge or awareness shall be limited to the actual knowledge or awareness at the Effective Date (without having made any searches or enquiries, other than of UCLB's Biopharm marked database) of the senior management team of UCLB (director status and above).
- 18.4 Save for the warranties and representations expressly set forth above by reference to Schedule 9, (i) the Parties exclude all other warranties and representations of any kind, whether express or implied in connection with this Agreement, save that the foregoing shall not exclude or limit any liability for fraud or fraudulent misrepresentation and (ii) without prejudice to the above, UCLB does not give any warranty, representation or undertaking:
- 18.4.1 as to the efficacy, usefulness, fitness for purpose, quality, safety or commercial or technical viability of the Technology and/or any Royalty Products;
- 18.4.2 that any of the Licensed Patents are or will be valid or will proceed to grant.

19. **LIMITATION OF LIABILITY**

Special, Indirect and Other Losses

- 19.1 In no event shall any Party or any of their respective Affiliates be liable for breach of contract, statutory duty, negligence or in any other way for special, indirect, incidental, punitive or consequential damages or for any indirect economic loss or indirect loss of profits suffered by any other Party or their respective Affiliates.

No Exclusion

- 19.2 UCLB's total aggregate liability to Liverco for any and all loss or damage suffered by Liverco as a result of breach of or otherwise in connection with this Agreement in respect to any and all claims arising under this Agreement shall be limited to [**] provided that in the event that any breach of warranty 1.1.5 and/or 1.1.6 of Schedule 9 gives rise to loss suffered by Liverco in excess of this cap, the cap shall be increased to the sum of [**] such that UCLB's total aggregate liability for any and all claims arising under or in connection with this Agreement shall be limited to the sum of [**]
- 19.3 Nothing in this Agreement shall limit or be construed to limit in any way any liability a Party (or its respective Affiliates) may have to the other Party (or its Affiliates) under this Agreement in respect of (i) death or personal injury caused by that Party's (or its respective Affiliates') negligence; (ii) any fraud or fraudulent misrepresentation or (iii) any other liability which, by rule of law, may not be excluded or limited by contract between parties.

20. **INDEMNITY AND INSURANCE**

- 20.1 Subject to Clause 20.3, Liverco shall indemnify and hold harmless UCLB and/or its Affiliates and any officers, employees, contractors and/or consultants of UCLB and/or its Affiliates (each a “**Indemnified Party**” and together the “**Indemnified Parties**”), from and against any and all Third Party (excluding any of the Indemnified Parties) claims, proceedings, liabilities, damages and expenses (including, reasonable legal fees) arising from or in connection with Liverco’s and/or its Sub-Licensees’ exercise of any of the rights granted to Liverco hereunder. Each of the foregoing Third Party claims, proceedings, liabilities, damages and expenses (including, reasonable legal fees) being an “**Indemnity Claim**”. Notwithstanding the foregoing, if Liverco indemnifies any Indemnified Party under the terms of the [**] then Liverco shall not be obliged to indemnify such Indemnified Party for those same losses under this Agreement.
- 20.2 Liverco’s obligation to indemnify the Indemnified Parties in respect of an Indemnity Claim is dependent upon compliance with the following provisions:
- 20.2.1 promptly after receipt by an Indemnified Party of any claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation to which the indemnity provided for in Clause 20.1 may apply, UCLB or the Indemnified Party shall give written notice to Liverco of such fact and provide all information available to it and relevant to the Indemnity Claim to Liverco;
- 20.2.2 the Indemnified Party shall permit Liverco to have sole control, conduct, defence and settlement of the Indemnity Claim and shall not make any admission or reach any settlement with the Third Party other than at Liverco’s written direction or with Liverco’s prior written consent;
- 20.2.3 the Indemnified Party shall co-operate in good faith with Liverco in the conduct of any defence or settlement and shall provide reasonable assistance and do all things as may be reasonably required to enable any Indemnified Claim to be defended and shall provide promptly to Liverco (i) copies (or originals where available) of all correspondence and documents relevant to the Indemnified Claim; (ii) reasonable access to all personnel of the Indemnified Party (including its consultants) to assist with defence of the Indemnified Claim and (iii) all other information, documents or assistance as may be reasonably required;
- 20.2.4 Liverco shall have the right at its sole discretion to bring any counterclaim in the name of any Indemnified Parties provided it first notifies the applicable Indemnified Parties of its intention to bring such counterclaim;
- 20.2.5 Liverco shall have the right at its sole discretion to settle or compromise any Indemnity Claim except that Liverco shall not without the prior written consent of the Indemnified Party:
- 20.2.5.1 admit any liability on the part of any Indemnified Party; or,

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

- 20.2.5.2 in respect of any product liability claims the subject of the Indemnity Claim, not make any public statement that amounts to any admission of wrongdoing on the part of the Indemnified Party.
- 20.2.6 Should any damages, financial remedy, costs or other recovery be made in favour of the Indemnified Party or Liverco, such sums shall be for the sole account of Liverco.
- 20.3 Liverco shall consult with the Indemnified Party on the defence and/or settlement of any Indemnified Claim and in so far as is reasonable, Liverco shall consider any reasonable suggestions of the Indemnified Party in the conduct of the defence or settlement of the Indemnity Claim.
- 20.4 Should Liverco assume conduct of the defence, the Indemnified Party may retain separate legal advisers at its sole cost and expense, save that if Liverco denies the applicability of the indemnity or reserves its position in relation to the same, the indemnity in Clause 20.1 shall extend to the Indemnified Party's costs and expenses so incurred if Liverco's position is established to be substantively incorrect.
- 20.5 Upon termination or expiry of this Agreement, Liverco's obligation to provide an indemnity to the Indemnified Parties pursuant to Clause 20.1 for any actions or proceedings shall expire [**] after the termination or expiry of the Agreement, save in respect of any [**]
- 20.6 Liverco shall maintain, at its own cost, comprehensive and customary insurance including product liability insurance in an amount and for a period sufficient to cover Liverco's liabilities under this Agreement. Once per annum, Liverco shall upon UCLB's request, provide UCLB with a copy of the latest certificate evidencing the coverage required hereby, and the amount thereof. Such insurance shall be with a reputable insurance company.
21. **TERMINATION**
- 21.1 This Agreement shall take effect on the Effective Date and shall continue thereafter unless and until terminated in accordance with this Clause 21 or if earlier until such time as the Royalty Term in each country in the Territory has expired and no further Milestone Payments are due, in which case all Licences, the Manufacturing Licence and UCL Background Licence granted hereunder shall automatically convert to a perpetual, irrevocable, royalty free, fully paid up, assignable licence (the "**Term**").
- 21.2 The Parties may, by mutual written agreement, agree that this Agreement be terminated in whole or on a Program Licence by Program Licence basis.
- 21.3 Liverco may terminate this Agreement upon thirty (30) days prior written notice to UCLB on a (i) Program Licence by Program Licence basis; or (ii) in respect of [**] Vector Licence; or (iii) in respect of all Licences.

- 21.4 Either Party (a “**Non-Defaulting Party**”) may terminate this Agreement (without prejudice to its other rights and remedies) with immediate effect by written notice to the other Party (the “**Defaulting Party**”) if:
- 21.4.1 the Defaulting Party commits a material breach of its material obligations under this Agreement (it being acknowledged that UCLB may not terminate under this Clause for any breach of Clause 9) and, if the breach is capable of remedy, fails to remedy it during the longer period of (i) a hundred and eighty (180) days or (ii) such other period as the Parties may, acting in good faith having regard to the nature of the breach and the time required to remedy the same, agree in writing (the “**Notice Period**”), in each case starting on the date of receipt of notice from the Non-Defaulting Party which specifies the breach in reasonable detail and requires it to be remedied. If the Defaulting Party in good faith disputes that it has committed a material breach under this Agreement, or that it has not cured the claimed breach within the Notice Period, it may refer the matter to the dispute resolution procedure under Clause 30 provided that the termination shall not be effective until conclusion of all dispute resolution procedures pursued by any Party including any proceedings before a court to determine the validity of the termination notice; or
- 21.4.2 the Defaulting Party suffers an Insolvency Event.
- 21.5 Without prejudice to Clause 21.4, UCLB may (unless the non-payment is remedied in the 30 day period) terminate this Agreement upon thirty (30) days’ prior written notice if Liverco has not paid sums in [**] which are properly due under this Agreement, provided that the sums are not subject to a bona fide dispute between the Parties. In the event of a payment dispute:
- 21.5.1 each Party shall provide the other with written reasons as to why it believes any disputed sums are either not payable or payable (as applicable):
- 21.5.2 the Parties shall attempt to resolve the payment dispute by following the escalation process for dispute resolution set out in Clause 30.2; and
- 21.5.3 where the Parties are unable to resolve the payment dispute by way of the escalation process set out in Clause 30.2, the Parties shall seek to resolve the dispute by following the dispute resolution procedure set out in Clauses 30.3 and/or 30.9.
- 21.6 Following resolution of any payment dispute, Liverco shall pay UCLB any amount agreed or adjudged to be due, together with interest thereon, such interest shall be payable at a rate of [**] over the Bank of England base rate, for the period from when such amount was originally due until the date that UCLB receives the agreed or adjudged sums. If Liverco fails to pay UCLB the requisite payment within [**] of the date of receipt of invoice from UCLB requesting the agreed or adjudged sums, UCLB shall be entitled to terminate this Agreement with immediate effect by written notice at the end of the [**] period.

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- 21.7 If the disputed amount is a part of a larger payment, Liverco shall pay UCLB the non-disputed amount no later than [**] after receipt of the invoice from UCLB requesting the non-disputed amount, failing which UCLB shall be entitled to terminate the Agreement pursuant to the provisions of Clause 21.5.
- 21.8 The Parties shall continue to perform their obligations under this Agreement, notwithstanding any dispute between the Parties with respect to payment.
- 21.9 Save as provided under this Clause 21 (but without prejudice to UCLB's rights of termination under Clause 9.10), the Parties shall have no other right to terminate this Agreement including under any right according to common law.

22. CONSEQUENCES OF TERMINATION

- 22.1 Upon termination of a Program Licence under Clause 21, other than the Background Licence granted pursuant to Clause 2.1.2 and the Manufacturing Licence granted pursuant to Clause 2.2.2:
- 22.1.1 the applicable Program Licence shall automatically terminate; and,
- 22.1.2 Liverco shall cease to have rights under this Agreement under such Program Licence.
- 22.2 Upon termination of a Program Licence under Clause 9.10 or 9.12 other than the Background Licence granted pursuant to Clause 2.1.2 and the Manufacturing Licence granted pursuant to Clause 2.2.2:
- 22.2.1 the applicable Program Licence shall automatically terminate;
- 22.2.2 Liverco shall cease to have rights under this Agreement under such Program Licence; and
- 22.2.3 the provisions of Clause 9.11 shall apply.
- 22.3 Upon termination of this Agreement as a whole under Clause 21:
- 22.3.1 all Licences other than the Background Licence granted pursuant to Clause 2.1.2 and the Manufacturing Licence granted pursuant to Clause 2.2.2 shall automatically terminate;
- 22.3.2 Liverco shall cease to have rights under this Agreement in respect of the Program Licences;
- 22.3.3 Where termination is effected by UCLB for Liverco's breach or by LiverCo being subject to an Insolvency Event, UCLB shall have the option to negotiate with Liverco to agree terms for the grant of a licence [**] specific to the Product that was the subject of the terminated Licences, such option and negotiation rights to expire [**] following notice of termination served under Clause 21.

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- 22.4 The termination of any Licence hereunder shall be without prejudice to the survival of any sub-licence novated to UCLB pursuant to the conditions under Clause 3.3.3.
- 22.5 Termination or expiry of this Agreement for whatever reason shall not affect the accrued rights (including those relating to any payments due or payable hereunder) of any Party arising under or out of this Agreement at the date of termination or expiry and all provisions which are expressed to survive this Agreement or continue after the Term and the provisions of Clauses 3.3.3, 15.11, 19, 20, 22, 27, 28 and 30 shall survive termination or expiry and remain in full force and effect
23. **FORCE MAJEURE**
- 23.1 In this Agreement “force majeure” shall mean any cause preventing a Party from performing any or all of its obligations (other than an obligation to pay sums due) which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the Party so prevented including to the extent that these are beyond such control industrial disputes, nuclear accident or acts of God, war or terrorist activity, riot, civil commotion, malicious damage, accident, fire, flood, storm.
- 23.2 If a Party is prevented from performance of any of its obligations under this Agreement by force majeure, that Party shall as soon as reasonably possible serve notice in writing on the other Parties specifying the nature and extent of the circumstances giving rise to force majeure, and shall subject to service of such notice have no liability in respect of any delay in performance or any non-performance of any such obligation save for any payment obligation which shall continue in full force and effect (and the time for performance shall be extended accordingly) to the extent that the delay or non-performance is due to force majeure.
- 23.3 If a Party is prevented from performance of substantially all or all of its obligations by force majeure for a continuous period of more than [**] in total, the other Party may terminate this Agreement forthwith on service of written notice upon the Party so prevented, in which case the Parties shall not have any liability to the other except that rights and liabilities which accrued prior to such termination shall continue to subsist.
24. **FURTHER ASSURANCE**
- 24.1 During the Term, UCLB shall at its own cost execute all such documents and do or cause to be done all such other things as Liverco may from time to time require in order to:
- 24.1.1 enable and provide Liverco with the benefit of the Licences granted to it hereunder; and,
- 24.1.2 otherwise to give full effect to this Agreement.

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- 24.2 During the Term UCLB shall comply with its obligations under Clauses 7.1 to 7.5 so it may facilitate Liverco using its commercially reasonable endeavours in accordance with its obligations under Clause 9.
- 24.3 Without limiting its obligations under Clause 24.1, UCLB shall complete (or procure the completion of) such documents and take such other steps as shall be necessary or desirable to enable Liverco to be recorded on any registry as the licensee of the Intellectual Property licensed to it hereunder.
- 24.4 UCLB shall procure the assistance of UCL and require UCL to do or refrain from doing things which would otherwise constitute a breach of the terms of this Agreement.

25. **PUBLICITY**

- 25.1 Upon execution of this Agreement, UCLB shall not make any press release regarding this transaction or the Technology licensed hereunder other than with the prior agreement of Liverco after the first press release. [**] shall have sole discretion as to the timing and content of the initial press, provided that UCLB shall be consulted on the content of that press release. Thereafter, Liverco shall have the right to make such press releases as it deemed appropriate, but in doing so shall not make reference to UCLB or UCL in such press release that is not approved (such approval not to be unreasonably withheld or delayed) by UCLB (for itself and on behalf of UCL), unless the reference is in a sentence that has previously been approved by UCLB in which case Liverco may reproduce the same sentence without requiring further consent. Notwithstanding anything in this Agreement to the contrary, a Party shall not be prevented from complying with its statutory obligations to make public statements regarding this Agreement, its subject matter or developments under this Agreement pursuant to the rules of any stock market or other laws applicable to it.
- 25.2 In order to enable UCLB and UCL to monitor the benefit that they are providing, and to enable UCL to demonstrate the impact of its research activities, to society and the economy, as reasonably requested by UCLB, Liverco shall provide to UCLB non confidential information on how it has used the Technology and the societal and economic benefits generated therefrom.
- 25.3 Liverco acknowledges that UCLB and UCL shall be entitled to make use of any information received from Liverco (and the information contained therein) pursuant to Clause 25.2 in applications for research or other granted related funding and in submissions to Higher Education funding bodies such as HEFCE and/or HEIF (or any replacements for either of those entities) and like entities, and to use Liverco's name in their general publicity materials subject to Liverco's prior written approval.

26. **ASSIGNMENT**

- 26.1 Save as provided in this Clause 26, neither Party shall without the prior written consent of the other Party assign any of its rights or obligations under this Agreement, or purport to do any of the same. Any purported assignment in breach of this Clause shall confer no rights on the purported assignee.

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- 26.2 Subject to Clause 26.3 and 26.4, Liverco shall be entitled to assign its rights together with its obligations under this Agreement to any Affiliate of Liverco or to any acquirer of all or substantially all of Liverco's business provided that such assignee agrees in writing to be bound by all of the terms and conditions of this Agreement and provided also that the provisions of Clause 3.1 and 3.2 shall apply with respect to any proposed assignment as if it were a sub-licence. No assignment shall be valid or effective unless or until the assignee shall agree, in writing, to be bound by the provisions of this Agreement.
- 26.3 Without prejudice to UCLB's right to terminate the Agreement pursuant to Clause 21.4.2 (where Liverco suffers an Insolvency Event), Liverco may grant security over or assign by way of security any of its rights and obligations under this Agreement provided that any such assignment shall comply with the provisions of Clause 26.2.
- 26.4 Liverco shall not be entitled to assign the Agreement during the grace periods [**] referred to in the definition of Insolvency Event and any assignment of the Agreement during this period shall not be valid or effective.
- 26.5 UCLB shall not assign any of the Technology to any Third Party nor grant any mortgage, charge or other encumbrance over the Technology.

27. **NOTICES**

- 27.1 All notices required to be served by the Parties to this Agreement under the terms hereof shall be sufficiently served if dispatched by first class post or commercial courier to the addresses of each of the Parties set out below. All such notices shall be deemed received within [**] after such dispatch.

If to:

Liverco c/o [**]

UCLB The Network Building, 97 Tottenham Court Road, London, W1T 4TP

and any modification or amendment to such address must itself be notified in writing to the other Parties in accordance with the terms of this Clause.

28. **MISCELLANEOUS PROVISIONS**

Entire Agreement

- 28.1 This Agreement and any variations, amendments or other modifications in relation to this Agreement constitutes the entire agreement between the Parties relating to its subject matter and save for the CDA supersedes all prior agreements and understandings, both written and oral, between the Parties with respect to the Programs, the Program IP, the Manufacturing Know-How and the UCL Background IP.
- 28.2 Each Party acknowledges that in entering into this Agreement it does not do so on the basis of and does not rely on any representation, warranty, or other provision except as

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expressly provided in this Agreement and all conditions, warranties and other terms implied by statute or common law are hereby excluded to the fullest extent permitted by law provided that nothing in this Clause should be construed as limiting or excluding liability for fraud.

28.3 Except as otherwise provided in this Agreement, the only remedy available to a Party for breach of this Agreement shall be for breach of contract under the terms of this Agreement and no Party shall be liable in tort or otherwise arising from such breach. The rights and remedies provided by this Agreement are cumulative and (except as otherwise provided in this Agreement) are not exclusive of any rights or remedies provided by law.

28.4 Nothing in this Clause 28 shall limit or exclude any liability for fraud or fraudulent misrepresentation.

Amendment and Waiver

28.5 Any agreement to amend, vary or modify the terms of this Agreement in any manner shall be valid only if the amendment, variation or modification is effected in writing and signed by duly authorised representatives of each of the Parties hereto.

28.6 No delay by any Party in enforcing any of the provisions of this Agreement shall be deemed a waiver of that Party's right subsequently to enforce such provision.

Severability

28.7 If any term or provision of any part thereof contained herein shall be declared or become unenforceable invalid or illegal in any respect under the law of any relevant jurisdiction:

28.7.1 such term or provision or part thereof shall be deemed to have been severed from the remaining terms of this Agreement and the terms and conditions hereof shall remain in full force and effect as if this Agreement had been executed without the offending provision appearing herein; and

28.7.2 the Parties shall endeavour to agree an amendment which to the fullest extent possible will give lawful effect to their intentions as expressed in any term or provision severed under Clause 28.7.1

28.7.3 If any restriction in this Agreement is held by any court or other competent authority to be invalid or unenforceable, then the Party against whom such restriction was intended to apply agrees to be bound by a restriction the same as the terms of the most onerous restriction which the court or other competent authority would have allowed in place of the affected restriction.

Status of the Parties

- 28.7.4 Except as otherwise provided, each Party shall bear its own costs and expenses in connection with the preparation, negotiation, execution and performance of this Agreement and the documents referred to in it.
- 28.7.5 No Party is authorised to act as the agent of the other for any purpose whatsoever and no Party shall on behalf of the other(s) enter into, or make, or purport to enter into or make or represent that it has any authority to enter into or make any representation or warranty.
- 28.7.6 Nothing in this Agreement shall be deemed to constitute a partnership or joint venture company between any or all of the Parties and none of the Parties shall do or suffer to be done anything whereby it might be represented as a partner of the other Parties.
- 28.7.7 Each Party shall be directly responsible to the other Parties for all actions or omissions of its respective Affiliates, agents and sub-contractors relating to the subject matter of this Agreement and shall be responsible for and liable for the fulfilment and observance by itself and its Affiliates, agents and sub-contractors of the applicable obligations and restrictions on it and its Affiliates, agents and sub-contractors hereunder (or to be imposed on them pursuant to the terms hereunder).
- 28.7.8 A person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement but this does not affect any right or remedy of a Third Party which exists or is available apart from that Act. Notwithstanding the above, (i) an Indemnified Party which is not a Party to this Agreement may enforce the provisions of Clause 20.1 where it has the benefit of the indemnity provided in Clause 20.1; and (ii) [**] and the Appointed Expert may enforce the provisions of Clause 3.2.3. The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any person that is not a Party to this Agreement, including any Indemnified Party or [**] or the Appointed Expert, provided that the Parties may not vary or waive the rights of [**] or the Appointed Expert under Clause 3.2.3 without their prior written consent.

29. **COUNTERPARTS**

This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which shall be an original but all of which together shall constitute one and the same instrument, and shall not be effective until each of the Parties has executed at least one counterpart.

30. **DISPUTE RESOLUTION, GOVERNING LAW AND JURISDICTION**

- 30.1 All controversies or claims of whatever nature arising out of or relating in any manner whatsoever to this Agreement or any of the documents referred to in this Agreement, including but not limited to a controversy or claim involving the validity, enforceability, interpretation or construction of this Agreement or any of the documents referred to in this Agreement, shall be governed by and construed in all respects in accordance with the laws of England.
- 30.2 In the event of any dispute, difference or question arising in connection with this Agreement, either Party shall be entitled but not obliged to escalate the matter to the Parties' Executive Officers by serving a written notice on the other Party's Executive Officer, in which case the Parties' Executive Officers shall make themselves available to discuss the dispute, difference or question, as the case may be (the "Unresolved Matter"), and use good faith efforts to resolve such Unresolved Matter within the [**] following the delivery of such notice.
- 30.3 If the Parties agree to submit, they shall submit to non-binding mediation by a neutral mediator (with the understanding that the role of the mediator shall not be to render a decision but to assist the Parties in reaching a mutually acceptable resolution) who shall be accredited by the Centre of Dispute Resolution ("CEDR") or otherwise appropriately qualified, and the mediation regarding the Unresolved Matter shall take place in London UK (or such other location as may be mutually agreed upon by the Parties). The mediator shall be chosen by agreement of the Parties, or if they are unable to agree on a mediator within [**] of a request from one Party to the other or if the agreed mediator is unable or unwilling to act, either Party may apply to CEDR to appoint a mediator.
- 30.4 Within [**] of the mediator being appointed, the Parties shall seek guidance from the mediator on a programme for the exchange of information and the structure to be adopted for negotiations. Either Party may request a preliminary meeting with the mediator for this purpose which shall be attended by both Parties.
- 30.5 Unless otherwise agreed, all negotiations concerning the dispute shall be conducted in confidence and shall be without prejudice to the rights of the parties in any future proceedings. The mediation is non-binding and Parties shall not be obliged to accept or follow any recommendation of the mediator.
- 30.6 If the Parties reach agreement on the resolution of the dispute, the agreement shall be reduced to writing and shall be binding on the Parties once it is signed by their duly authorised representatives.
- 30.7 If the Unresolved Matter is not resolved by mediation within [**] of appointment of the mediator, either Party may, subject to Clause 30.9, make any claim or application before the court as it sees fit.
- 30.8 Notwithstanding the provisions of Clause 30.2 or of Clause 30.3, subject to Clause 30.9, each Party shall be free to seek temporary injunctive relief in court as the situation may necessitate based upon any irreparable harm which may ensue.

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30.9 Each Party acknowledges and agrees that the courts of England shall have exclusive jurisdiction to resolve any controversy or claim of whatsoever nature arising out of or relating in any manner to this Agreement, any terms of this Agreement, or any breach of this Agreement or any such terms.

[Remainder of this page is intentionally blank]

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IN WITNESS WHEREOF, the Parties hereto have caused their duly authorised officers to execute and acknowledge this Agreement as of the date first written above.

SIGNED by a director on behalf of) *Signature* _____
FREELINE THERAPEUTICS LIMITED)
) *Print Name* _____

SIGNED by a director on behalf of) *Signature* _____
UCL BUSINESS PLC)
) *Print Name* _____

I, Amit Nathwani, of [**] have read, understand and accept the provisions of this Agreement and how it relates to my research and the AN Laboratory.

Signed _____

Date: _____

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SCHEDULE 1

The Programs

[**]

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SCHEDULE 2

Program IP, Sequence Data, Constructs and Program Materials

[**]

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SCHEDULE 3

UCL Background

[**]

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SCHEDULE 4

Manufacturing Know-How

[**]

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SCHEDULE 5

Disclosure Process

[**]

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SCHEDULE 6

Part A: Existing Licenses

[**]

Part B: Commercial Agreements

None

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SCHEDULE 7

Permitted Studies

This schedule is not applicable.

SCHEDULE 8

Part A: Net Sales Definition

[**]

Part B: Expert Procedure

1. Any dispute arising out of or in connection with Clause 13.11 of this Agreement and paragraphs 3, 4, 5, 6 or 7 of Part A of Schedule 8 to this Agreement and/or its performance shall be referred to an expert by either Party serving on the other Party notice (“**Referral Notice**”) that it wishes to refer the dispute to an expert. For the avoidance of doubt, no reference shall be made to the expert as to what product or therapy constitutes a Royalty Product and any dispute in that regard shall be determined in accordance with Clause 30.3 and/or Clause 30.9 of the Agreement. If either Party challenges whether a product or therapy constitutes a Combination Product that dispute shall be determined in accordance with Clause 30.3 and/or Clause 30.9 of the Agreement.
2. The dispute shall be determined by a single independent impartial expert who shall be agreed between the Parties or, in the absence of agreement between the parties within [**] of the service of a Referral Notice, be appointed by the then President of the Institute of Chartered Accountants or any successor organisation thereto.
3. The seat of the dispute resolution shall be the normal place of residence of the expert.
4. The language of the dispute resolution shall be English.
5. The expert shall not have power to alter, amend or add to the provisions of this Agreement, except that the expert shall have the power to decide all procedural matters relating to the dispute, and may call for a one day hearing if desirable and appropriate.
6. The expert shall have the power to request copies of any documents in the possession and/or control of the parties which may be relevant to the dispute. The parties shall forthwith provide to the expert and the other party copies of any documents so requested by the expert.
7. The expert shall decide the dispute as an expert and not as an arbitrator.
8. The decision of the expert shall be final and binding upon both parties except in the case of manifest error. The parties hereby exclude any rights of application or appeal to any court, to the extent that they may validly so agree, and in particular in connection with any question of law arising in the course of the reference out of the award.
9. The expert shall determine the proportions in which the parties shall pay the costs of the expert’s procedure. The expert shall have the authority to order that all or a part of the legal or other costs of a party shall be paid by the other party. UCLB’s liability in this regard shall not be subject to the cap on liability under Clause 19.
10. All documents and information disclosed in the course of the expert proceedings and the decision and award of the expert shall be kept strictly confidential by the recipient and shall not be used by the recipient for any purpose except for the purposes of the proceedings and/or the enforcement of the expert’s decision and award.

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Part C: Net Receipts Definition

[**]

SCHEDULE 9

Warranties and Covenants

Part A: Mutual Warranties & Representations

- 1.1 In respect of each Party making the warranty and representation:
 - 1.1.1 it is a company duly organised, validly existing, and in good standing under the laws of England;
 - 1.1.2 it has full corporate power and authority to execute, deliver, and perform this Agreement and has taken all corporate action required by law and its organisational documents to authorise the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;
 - 1.1.3 this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, insolvency or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity);
 - 1.1.4 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement and the consummation of the transactions contemplated hereby and thereby do not and shall not (i) conflict with or result in a breach of any provision of its organisational documents, (ii) result in a breach of any agreement to which it is a party; or (iii) violate any law.

Part B: UCLB Warranties & Covenants as of the Effective Date

2. UCLB warrants and represents to Liverco that as of the Effective Date:

Material Information

- 1.1.1 the information set out in the Schedules as of the Effective Date is accurate and so far as UCLB is aware is materially complete;
- 1.1.2 all the information which is contained in the Disclosure Letter dated as of the Effective Date and the documents (if any) annexed to it is complete and accurate and not misleading;

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 1.1.3 each statement of opinion or belief which is attributed in the Disclosure Letter dated as of the Effective Date is honestly held by the members of the UCLB senior management team;
- 1.1.4 each document if annexed to the Disclosure Letter dated as of the Effective Date is a complete and accurate copy of the original, and no such document has been amended (orally or in writing) or superseded;

Intellectual Property

- 1.1.5 it is the sole and exclusive owner, free of all encumbrances, of all right, title and interest in and to the Original Licensed Patents;
- 1.1.6 in respect of the Original Program IP, Manufacturing Know-How and, in so far as it existed at the Effective Date, the UCL Background IP, in each case it is either:
 - 1.1.6.1 the sole and exclusive owner, free of all encumbrances, of all right, title and interest in and to such Intellectual Property; or
 - 1.1.6.2a licensee with the right to grant the licences granted herein on the terms granted herein in respect of such Intellectual Property;
- 1.1.7 it has not granted, or agreed to grant, any licences or entered into any agreements which may adversely affect or conflict with this Agreement and/or with any of the Original Licences granted hereunder and/or options to licences granted hereunder;
- 1.1.8 it has not granted, or agreed to grant, any assurance or waiver not to enforce in respect of any of the Intellectual Property exclusively licensed hereunder in so far as such consents, assurances or waivers would enable the Third Party to develop, free of infringement, any product or therapy that is Covered by or has been developed using or uses any of the Intellectual Property exclusively licensed hereunder;
- 1.1.9 there is no other Patent Right (beyond the Original Licensed Patents) owned by UCLB as at the Effective Date that is required for the use and practise of any of the Original Program IP, Manufacturing Know-How or, in so far as it existed at the Effective Date, the UCL Background IP, having regard to UCLB's understanding of Liverco's development plan for the period of [**] after the Effective Date;
- 1.1.10 as at the Effective Date no invention disclosure forms have been logged in UCLB's database and categorised as "Biopharm" and with the status "being assessed", disclosing patentable inventions in respect of which (if patent applications were filed for such inventions within [**] of the Effective Date) to the best of UCLB's knowledge and belief a licence would be required for the use and practise of any of the Original Program IP, Manufacturing Know-How or, in so far as it existed at the Effective Date, the UCL Background IP, having regard to UCLB's understanding of Liverco's development plan for the period of [**] after the Effective Date;

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 1.1.11 it has provided Liverco with details of Third Party Patent Rights of which it is aware, and which to the best of its knowledge and belief not having (i) conducted any professional freedom to operate searches or (ii) sought advice from a qualified patent attorney or solicitor, may be relevant to the development of any Original Royalty Product on the basis of UCLB's understanding of Liverco's development plan for the period of [**] after the Effective Date;
- 1.1.12 it is not aware that the disclosure to Liverco of Know-How forming part of the Original Program IP, Manufacturing Know-How or, in so far as it existed at the Effective Date, the UCL Background IP will amount to a breach of any obligation of confidentiality owed by UCL, AN or UCLB to any Third Party;
- 1.1.13 it is not aware of any material breach by UCLB, UCL or AN of any Third Party contracts set out in Schedule 6;
- 1.1.14 it has not received any negative opinion from any patent office as to the validity of the Original Licensed Patents;
- 1.1.15 there is no on-going litigation to which UCL or UCLB is a party concerning any of the Original Program IP, Manufacturing Know-How or, in so far as it existed at the Effective Date, the UCL Background IP;

Clinical Studies

- 1.1.16 there has been no clinical use of any of the Materials existing as of the Effective Date;

Laboratory Work

- 1.1.17 None of [**] or [**] have, prior to the Effective Date, worked on any project under the supervision of AN related to any of the Exclusive Field and that the Haemostasis Group has not carried out any work in relation to the Original Programs;
- 1.1.18 Beyond the gene transcription promoter with the sequence set out in Schedule 2 (HLP2) and the HLP1 Promoter Sequence, neither AN nor the AN Laboratory have been working on a new gene transcription promoter for application with any AAV-directed gene therapy product.

Promoter Patent Rights

- 1.1.19 the inter-institutional agreement between UCLB and [**] dated [**] provided to Liverco concerning the Promoter Patent Rights along with its first amendment dated [**] is complete and has not been amended, superseded or otherwise varied, and that the agreement is in full force and subsisting, and UCLB has not received any written notice alleging breach or to terminate the same nor is it aware of any breach of the same.

Part C: UCLB Warranties & Covenants as of the Amendment Date

3. UCLB warrants and represents to Liverco that as of the Amendment Date:

Material Information

1.1.1 the information set out in the Schedules with respect to the Additional Programs is accurate and so far as UCLB is aware is materially complete;

Intellectual Property

1.1.2 it is the sole and exclusive owner, free of all encumbrances, of all right, title and interest in and to the Additional Patent Rights and FX Vector IP;

1.1.3 in respect of the Additional Program IP and, in so far as it arose after the Effective Date, the UCL Background IP, in each case it is either:

1.1.3.1 the sole and exclusive owner, free of all encumbrances, of all right, title and interest in and to such Intellectual Property; or

1.1.3.2 a licensee with the right to grant the licences granted herein on the terms granted herein in respect of such Intellectual Property;

1.1.4 it has not granted, or agreed to grant, any licences or entered into any agreements which may adversely affect or conflict with any of the Additional Program Licences or FX Vector Licence granted hereunder;

1.1.5 it has not granted, or agreed to grant, any assurance or waiver not to enforce in respect of any of the Additional Program IP or FX Vector IP in so far as such consents, assurances or waivers would enable the Third Party to develop, free of infringement, any product or therapy that is Covered by or has been developed using or uses any of the Additional Program IP or FX Vector IP exclusively licensed hereunder;

1.1.6 there is no other Patent Right (beyond the Additional Patent Rights) owned by UCLB as at the Amendment Date that is required for the use and practise of any of the Additional Program IP or FX Vector IP or, in so far as it arose after the Effective Date, the UCL Background IP, having regard to UCLB's understanding of Liverco's development plan for the period of [**] after the Amendment Date;

1.1.7 as at the Amendment Date no invention disclosure forms have been logged in UCLB's database and categorised as "Biopharm" and with the status "being assessed", disclosing patentable inventions in respect of which (if patent applications were filed for such inventions within [**] of the Effective Date) to the best of UCLB's knowledge and belief a licence would be required for the use and

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

practise of any of the Additional Program IP or FX Vector IP or, in so far as it arose after the Effective Date, the UCL Background IP, having regard to UCLB's understanding of Liverco's development plan for the period of [**] after the Amendment Date;

- 1.1.8 it has provided Liverco with details of Third Party Patent Rights of which it is aware, and which to the best of its knowledge and belief not having (i) conducted any professional freedom to operate searches or (ii) sought advice from a qualified patent attorney or solicitor, may be relevant to the development of any Additional Royalty Product on the basis of UCLB's understanding of Liverco's development plan for the period of [**] after the Amendment Date;
- 1.1.9 it is not aware that the disclosure to Liverco of Know-How forming part of the Additional Program IP or FX Vector IP or, in so far as it arose after the Effective Date, the UCL Background IP will amount to a breach of any obligation of confidentiality owed by UCL, AN or UCLB to any Third Party;
- 1.1.10 it has not received any negative opinion from any patent office as to the validity of the Additional Patent Rights;
- 1.1.11 there is no on-going litigation to which UCL or UCLB is a party concerning any of the Additional Program IP or FX Vector IP or, in so far as it arose after the Effective Date, the UCL Background IP;

Laboratory Work

- 1.1.12 None of [**] or [**] have, prior to the Effective Date, worked on any project under the supervision of AN related to the [**] Program and that the Haemostasis Group has not carried out any work in relation to the Additional Programs.

SCHEDULE 10

Milestone and Royalty Statements

1. In respect of each country where Royalty Products were supplied during that Quarter:
 - 2.1 the Net Sales of each type of Royalty Product supplied expressed both in local currency and in British pounds sterling together with conversion rates used;
 - 2.2 the royalty rate applicable to each type of Royalty Product supplied in that country;
 - 2.3 the calculation of the royalties payable in respect of each type of Royalty Product; and
 - 2.4 the total amount of royalties payable in respect of that country;
2. For the world as a whole:
 1. the total amount of royalties payable under Clause 12.1;
 2. the amount of any reduction or deduction made pursuant to Clauses 12.5 to 12.12, inclusive; and
 3. the amount of any withholding tax deducted pursuant to Clause 13.8.
3. In respect of any Royalty Products supplied to which the provisions of paragraph 3 of Part A of Schedule 8 are applicable:
 - 3.1 the amount of each type of Royalty Product supplied; and
 - 3.2 the actual price at which the Royalty Products were supplied and the nature and value of any other consideration provided for the Royalty Products.
4. In respect of any Royalty Products supplied to which the provisions of paragraphs 4, 5, 6 or 7 of Part A of Schedule 8 are applicable:
 - 4.1 the amount and description of any Combination Product or any packages of products or services supplied; and
 - 4.2 the actual price at which the package of any Combination Product or any products or services were supplied and the proportion of the sales price attributed to the Royalty Product in the relevant supply contract.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SCHEDULE 11

HLP1 Promoter Licence Term and [] Toxicology and Study Data**

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SCHEDULE 12

Capsid Sequences

[**]

THIS DEED OF VARIATION is made as of 24 January 2017

BETWEEN

- (1) **FREELINE THERAPEUTICS LIMITED**, a company duly organised and validly existing under the laws of England (company number 9500073) with its registered office at 215 Euston Road, London, NW1 2BE ("**Freeline**"); and
- (2) **UCL BUSINESS PLC**, a public company duly organised and validly existing under the laws of England (company number 02776963) with its registered office at The Network Building, 97 Tottenham Court Road, London, W1T 4TP ("**UCLB**") (each a "**Party**" and together the "**Parties**").

WHEREAS

- (A) The Parties entered into a Licence Agreement with effective date 22 May 2015 (the "**Agreement**").
- (B) The Parties wish to make certain changes to the Agreement as set out in this Deed (the "**Variation Agreement**").

IT IS NOW HEREBY AGREED AS FOLLOWS:

1. INTERPRETATION

For the purposes of this Variation Agreement, the following words and expressions shall have the following meanings:

"**Amendment Date**" means the date first written above.

"**Appendix**" means the appendix to this Variation Agreement.

In the event of any conflict between the terms of the Agreement (excluding this Variation Agreement) and the terms of this Variation Agreement then the terms of this Variation Agreement shall prevail and be applied.

2. AMENDMENTS TO THE AGREEMENT

The Parties hereby agree that with effect from the Amendment Date the terms of the Agreement shall be amended in accordance with the revisions shown to the Agreement in the Appendix and the Agreement will thereafter be read and construed in accordance with that amended form.

3. CONTINUING FORCE AND EFFECT

Save as varied by this Variation Agreement, the Agreement shall continue and remain in full force and effect. If the Agreement terminates for any reason, this Variation Agreement will automatically terminate at the same time.

4. MISCELLANEOUS

This Variation Agreement may be executed in one or more counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart by facsimile shall be as effective as delivery of the original.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

The Agreement and this Variation Agreement constitutes the entire agreement between the Parties relating to their subject matter and supersedes any previous agreement between the Parties relating to such matter.

Neither Party has relied upon any promise, condition, representation or warranty, express or implied, to enter into this Variation Agreement, other than those warranties set out in the Agreement as amended hereunder.

Nothing in this Variation Agreement, nor the amendment of the Agreement, waives, discharges, releases or in any other way excuses or excludes any Party's obligations or liabilities in respect of any accrued liabilities or breaches under the Agreement.

None of the provisions of this Variation Agreement may be changed, modified, waived or cancelled orally or otherwise, except by writing, in the manner provided in the Agreement, specifying such change, modification, waiver or cancellation of such terms or conditions, or of any proceeding or succeeding breach thereof.

[Remainder of this page intentionally blank]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

5. GOVERNING LAW

This Variation Agreement shall be governed by, interpreted and construed in accordance with English Law and any dispute, controversy or claim arising out of or in relation to this Agreement shall be subject to the exclusive jurisdiction of the English courts.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorised officers to execute, deliver and acknowledge this Deed as of the date first written above.

EXECUTED as a DEED by FREELINE

Signature [**] _____

) _____

THERAPEUTICS LIMITED acting by

)

_____, a

)

Print Name [**] _____

director, in the presence of:

[**] _____

Signature of Witness [**]

Name: [**]

Address: [**]

Occupation: [**]

EXECUTED as a DEED by UCL

Signature [**] _____

) _____

BUSINESS PLC, acting by

)

_____, a

)

Print Name [**] _____

director, in the presence of:

Executive Director

UCL Business PLC

[**] _____

Signature of Witness

Name : [**]

Address: [**]

Occupation: [**]

I, Amit Nathwani, of [**] have read, understand and accept the provisions of this Variation Agreement and how it relates to my research and the AN Laboratory.

Signed _____

Date: _____

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

5. GOVERNING LAW

This Variation Agreement shall be governed by, interpreted and construed in accordance with English Law and any dispute, controversy or claim arising out of or in relation to this Agreement shall be subject to the exclusive jurisdiction of the English courts.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorised officers to execute, deliver and acknowledge this Deed as of the date first written above.

EXECUTED as a DEED by FREELINE THERAPEUTICS LIMITED acting by [Name of Director], a director, in the presence of:) *Signature* _____
) _____
) *Print Name* _____

Signature of Witness
Name:
Address:
Occupation:

EXECUTED as a DEED by UCL BUSINESS PLC, acting by [Name of Director], a director, in the presence of:) *Signature* _____
) _____
) *Print Name* _____

Signature of Witness
Name :
Address:
Occupation:

I, Amit Nathwani, of [**] have read, understand and accept the provisions of this Variation Agreement and how it relates to my research and the AN Laboratory.

Signed [**] _____

Date: 24 January 2017

24 MAY 2018

**SECOND DEED OF AMENDMENT TO THE LICENCE
AGREEMENT DATED 22 MAY 2015**

- (1) FREELINE THERAPEUTICS LIMITED
- (2) UCL BUSINESS PLC

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

THIS SECOND DEED OF VARIATION is made as of the 24 day of May 2018 (“Second Amendment Date”)

BETWEEN

- (1) **FREELINE THERAPEUTICS LIMITED**, a company duly organised and validly existing under the laws of England (company number 9500073) with its registered office at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, UK (“**Freeline**”); and
- (2) **UCL BUSINESS PLC**, a public company duly organised and validly existing under the laws of England (company number 02776963) with its registered office at The Network Building, 97 Tottenham Court Road, London, W1T 4TP (“**UCLB**”) (each a “**Party**” and together the “**Parties**”).

WHEREAS

- (A) The Parties entered into a Licence Agreement with effective date 22 May 2015 which was amended pursuant to a Deed of Variation dated 24 January 2017 (collectively as amended the “**Agreement**”).
- (B) The Parties now wish to make certain further changes to the Agreement as set out in this Deed (the “**Second Variation Agreement**”).

IT IS NOW HEREBY AGREED AS FOLLOWS:

1. INTERPRETATION

For the purposes of this Second Variation Agreement, the following words and expressions shall have the following meanings:

“**Second Amendment Date**” means the date first written above.

In the event of any conflict between the terms of the Agreement (excluding this Second Variation Agreement) and the terms of this Second Variation Agreement, then the terms of this Second Variation Agreement shall prevail and be applied.

2. AMENDMENTS TO THE AGREEMENT

The Parties hereby agree that with effect from the Second Amendment Date the terms of the Agreement shall be amended in accordance with the following revisions and the Agreement will thereafter be read and construed in accordance with that amended form:

2.1 The following new definitions shall be inserted in the Agreement:

“**[**] Codop**” shall mean the nucleotide sequence of [**] having the sequence set out in Part E of Schedule 2 under the title [**]

“**FIX-[**] Patent Rights**” shall mean the patent applications filed by or on behalf of UCLB in agreement with Liverco claiming rights, inter alia, to the [**] Codop and [**] thereof and all Patent Rights derived therefrom;

2.2 The definition of FIX Patent Rights in the Agreement shall be amended to include the following language at the end of the definition:

“and, (iv) the **FIX-[**] Patent Rights**;”

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

2.3 The definition of FIX Program IP shall be amended to include the following language at the end of the definition:

*“and, (iii) all Know-How in the [**] Codop;”*

2.4 The definition of SSA shall be amended to replace the language “as of the Effective Date” with the following language:

“, as amended or replaced from time to time except where indicated to be as of the Effective Date;”

2.5 The words “*existing as of the Effective Date*” shall be inserted in Clause 3.8 within the parenthetical following “[**]”, after the words “[**]”.

2.6 The words “*existing as of the Effective Date*” shall be inserted in Clause 10.2 within the parenthetical after the words “is defined in the SSA”.

2.7 The relevant rows of the Royalty table set out at Clause 12.1 of the Agreement shall be amended as set out in the extract below:

A	[**]	[**]
---	------	------

2.8 A new row to the Royalty table set out at Clause 12.1 of the Agreement shall be added as set out in the extract below:

M	[**]	[**]
---	------	------

2.9 The following shall be incorporated into the Agreement at the end of Part E of Schedule 2:

[**]

[**]

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

[**]

2.10 UCLB shall only file Patent Rights that disclose or claim the [**] Codop (or a material part thereof) in consultation and agreement with Freeline.

3. TERMINATION OF RIGHTS & OBLIGATIONS TO THE ADDITIONAL PROGRAM IP

3.1 The Parties accept and acknowledge that, in accordance with Clause 21.2, this Deed serves with effect from the Second Amendment Date to terminate the [**] Licence and the [**] Licence, including all rights and obligations of the Parties relating to the [**] Product and [**] Program IP, and the [**] Product and [**] Program IP under the Agreement.

3.2 It is accepted and agreed by the Parties that with effect from the Second Amendment Date:

3.2.1 Freeline's rights and obligations under the Agreement regarding the Additional Products and Additional Program IP, including its obligation to pay any royalties or milestones in respect of any Additional Products or to pay for any patent prosecution costs, and all of Freeline's rights relating to the [**] Product and [**] Program IP and the [**] Product and [**] Program IP (including its rights to review any publications) shall terminate; and

3.2.2 without prejudice to the restrictions in respect of the Original Products or Freeline's Confidential Information, the restrictions on UCLB and UCL not to use or Exploit the [**] Product, [**] Program IP, the [**] Product and [**] Program IP shall terminate.

4. CONTINUING FORCE AND EFFECT

Save as varied by this Second Variation Agreement, the Agreement shall continue and remain in full force and effect. If the Agreement terminates for any reason, this Second Variation Agreement will automatically terminate at the same time.

5. MISCELLANEOUS

This Second Variation Agreement may be executed in one or more counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart by facsimile shall be as effective as delivery of the original.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

The Agreement and this Second Variation Agreement constitutes the entire agreement between the Parties relating to their subject matter and supersedes any previous agreement between the Parties relating to such matter.

Neither Party has relied upon any promise, condition, representation or warranty, express or implied, to enter into this Second Variation Agreement, other than those warranties set out in the Agreement as amended hereunder.

Nothing in this Second Variation Agreement, nor the amendment of the Agreement, waives, discharges, releases or in any other way excuses or excludes any Party's obligations or liabilities in respect of any accrued liabilities or breaches under the Agreement.

None of the provisions of this Second Variation Agreement may be changed, modified, waived or cancelled orally or otherwise, except by writing, in the manner provided in the Agreement, specifying such change, modification, waiver or cancellation of such terms or conditions, or of any proceeding or succeeding breach thereof.

[Remainder of this page intentionally blank]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

6. GOVERNING LAW

This Second Variation Agreement shall be governed by, interpreted and construed in accordance with English Law and any dispute, controversy or claim arising out of or in relation to this Agreement shall be subject to the exclusive jurisdiction of the English courts.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorised officers to execute, deliver and acknowledge this Deed as of the date first written above.

EXECUTED as a DEED by FREELINE THERAPEUTICS LIMITED acting by _____, a _____, a director, in the presence of:

) *Signature* _____
) _____
) *Print Name* _____

Signature of Witness
Name:
Address:
Occupation:

EXECUTED as a DEED by UCL BUSINESS PLC, acting by _____, a _____, a director, in the presence of:

) *Signature* [**]
) _____
) *Print Name* [**]
Executive Director
UCL Business PLC

[**]

Signature of Witness
Name: [**]
Address: [**]
Occupation: [**]

I, Amit Nathwani, of [**] read, understand and accept the provisions of this Second Variation Agreement and how it relates to my research and the AN Laboratory.

Signed _____

Date : _____

THIRD DEED OF AMENDMENT AND TERMINATION

between

UCL BUSINESS LTD

and

FREELINE THERAPEUTICS LIMITED

18/12/2019

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

THIS THIRD DEED OF AMENDMENT AND TERMINATION is made on 18/12/2019

BETWEEN:

- (1) **UCL Business Ltd** (formerly UCL Business PLC), a company registered in England under company registration number 02776963 whose registered office is at The Network Building, 97 Tottenham Court Road, London, W1T 4TP, United Kingdom (“**UCLB**”); and
- (2) **Freeline Therapeutics Limited**, a company incorporated and registered in England and Wales with company number 09500073 whose registered office is Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, England, SG1 2FX (the “**Company**”).

(the Company and UCLB each a “**Party**” and together the “**Parties**”).

WHEREAS:

- (A) The Parties to this deed (“**Deed**”) entered into a licence agreement with effective date 22 May 2015, which was amended on 24 January 2017 and 24 May 2018 (the licence agreement as amended from time to time, the “**Licence Agreement**”), pursuant to which UCLB licensed to the Company, among others, the [**] relation to the [**] for any act of Exploitation concerning any products, therapy, service or process without restriction or field limitation (such defined terms as defined in the Licence Agreement).
- (B) The Parties have now agreed to make certain further changes to the Licence Agreement in accordance with the terms of this Deed, in particular, the Parties wish to terminate [**] granted to the Company under the Licence Agreement, upon the terms and subject to the conditions set out below.

THIS DEED WITNESSES as follows:

1. INTERPRETATION

- 1.1 In this Deed, unless the context otherwise requires, words and expressions defined in the Licence Agreement and used in this Deed shall have the meaning set out in the Licence Agreement, unless otherwise provided.
- 1.2 In this Deed a reference to:
 - 1.2.1 a clause is a reference to a clause of this Deed;
 - 1.2.2 the singular includes the plural and vice versa;
 - 1.2.3 a statute or statutory provision includes a reference to that provision as modified, replaced, amended and/or re-enacted from time to time (whether before or after the date of this Deed) and any prior or subsequent subordinate legislation made under it (whether before or after the date of this Deed) except to the extent that any amendment, extension or re-enacting after the date of this Deed would extend or increase the liability of any party to the others under this Deed;
 - 1.2.4 an agreement or other document is a reference to that agreement or document as from time to time supplemented or amended.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 1.3 This Deed is supplemental to and varies the Licence Agreement and save as varied by this Deed, the provisions of the Licence Agreement shall continue in full force and effect.
- 1.4 In the event of any conflict between the terms of the Licence Agreement and the terms of this Deed then the terms of this Deed shall prevail and be applied.
- 1.5 The headings to the clauses in this Deed are for convenience only and shall not affect the interpretation or construction of this Deed.

2. TERMINATION OF THE FVII LICENCE

- 2.1 The Parties acknowledge that pursuant to Clause 28.5 of the Licence Agreement, the Licence Agreement can be amended if the amendment, variation or modification is effected in writing and signed by duly authorised representative of each Party.
- 2.2 Each Party acknowledges and agrees that as from the date of this Deed the terms of the Licence Agreement shall be amended in accordance with the provisions set out below and the Licence Agreement shall thereafter be read and construed in accordance with the following changes:
 - 2.2.1 the licence to the Company for the use of the [**] pursuant to the Licence Agreement shall terminate and, notwithstanding anything to the contrary in the Licence Agreement, clause 2.4.3 of the Licence Agreement shall cease to apply; and
 - 2.2.2 any rights, including all the obligations of the Parties, of the Company and its Affiliates in relation to [**] and, as the case may be, any sub-licences) granted pursuant to the Licence Agreement shall be null and of no effect.
- 2.3 The Company acknowledges and agrees:
 - 2.3.1 that as at the date of this Deed it has no claim or right of action (whether actual, contingent or prospective) against UCLB arising under or in connection with the [**] pursuant to the Licence Agreement;
 - 2.3.2 to release and discharge UCLB with effect from the date of this Deed from all actual, contingent or prospective obligations and liabilities (past, present or future) arising under or in connection with the [**] pursuant to the Licence Agreement or in connection with the subject matter of the [**] in relation to the performance of UCLB's obligations under the Licence Agreement, whether such claims arise in contract or in negligence;
 - 2.3.3 with effect from the date of this Deed to waive any claim or right of action (whether actual, contingent or prospective) which it has or may have (including, without limitation, claims for negligence) arising under or in connection with the [**] pursuant to the Licence Agreement, whether known or unknown as at the date of this Deed together with any related liability (whether past, present or future) against UCLB; and
 - 2.3.4 to the extent that any release or waiver by the Company set out in this clause is not effective, to indemnify and hold UCLB harmless for and against all losses and costs which UCLB may suffer or incur.
- 2.4 Notwithstanding the foregoing, UCLB acknowledges and agrees that it shall not grant to any third party any licence in respect of (i) any [**] (including the [**])

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

of the Licence Agreement) or (ii) any [**] which are an Improvement or New Invention under the Licence Agreement and were generated, reduced to practice or otherwise discovered or identified at any time from [**] up until and including [**] (“**New [**]**”) without first offering to the Company the right to take a licence from UCLB in respect of such [**] (“**New [**]**”), on terms to be agreed in good faith between the Parties. If, after a period of [**] from the date of UCLB first offering to the Company the right to take a [**], the Parties are not able to agree such terms, UCLB shall be free to grant such licence to any third party. For the avoidance of doubt, this clause 2.4 shall not apply to any [**] which does not constitute an Improvement or New Invention under the Licence Agreement.

3. COMPANY UNDERTAKINGS

- 3.1 The Company hereby warrants to UCLB that as at the date of this Deed no sums are due to UCLB in respect of the [**] under the Licence Agreement, in respect of the period prior to termination.
- 3.2 The Company shall at UCLB’s request execute any formal documents as may be necessary or appropriate to register the termination of the [**] granted under the Licence Agreement.

4. AMENDMENT OF THE LICENCE AGREEMENT

- 4.1 The Parties acknowledge and agree that pursuant to the termination of the [**] under the Licence Agreement, the Licence Agreement shall as from the date of this Deed be amended as required as a result of such termination, including by the deletion of any reference in relation to the [**].
- 4.2 The Parties acknowledge and agree that clause 16.2 of the Licence Agreement shall as from the date of this Deed be amended by the deletion of the words”, but excluding the Promoter Patent Rights”.
- 4.3 The Parties acknowledge and agree that notwithstanding the amendment of the Licence Agreement in accordance with clauses 4.1 and 4.2 above, the other provisions of the Licence Agreement shall remain valid to the maximum extent permitted under applicable law and save as amended in this Deed, shall continue in full force and effect.

5. FURTHER ASSURANCE

Each Party shall at its own cost do and execute or procure to be done and executed all necessary acts, Deeds, documents and things as may be reasonably requested of it by the other Party by written notice to give effect to this Deed.

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6. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

This Deed shall bind and is for the benefit of the successors in title of the Parties and, unless expressly stated otherwise in this Deed, a person who is not a party to this Deed shall have no rights under the Contracts (Rights of Third Parties) Act 1999 to rely upon or enforce any term of this Deed provided that this does not affect any right or remedy of the third party which exists or is available apart from that Act.

7. COUNTERPARTS

This Deed may be executed in any number of counterparts and by the different Parties on separate counterparts, each of which when so executed and delivered shall be an original but all counterparts shall together constitute one and the same instrument.

8. MISCELLANEOUS

8.1 This Deed (together with the Licence Agreement) sets out the entire agreement and understanding between the Parties in respect of the subject matter of the Licence Agreement.

8.2 None of the provisions in this Deed may be changed, modified, waived or cancelled orally or otherwise, except by writing in the manner provided in the Licence Agreement, specifying such change, modification, waiver or cancellation of such terms or conditions, or of any proceeding or succeeding breach thereof.

9. GOVERNING LAW AND JURISDICTION

9.1 This Deed and any dispute, claim or obligation (whether contractual or non-contractual) arising out of or in connection with it, its subject matter or formation shall be governed by and construed in accordance with English law.

9.2 The Parties irrevocably agree that the English courts shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) arising out of or in connection with this Deed, its subject matter or formation.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

IN WITNESS THIS DEED has been executed and delivered on the date appearing at the head of page 1.

EXECUTED as a Deed
For and on behalf of **UCL Business Ltd**

acting by a director)
)
_____)

in the presence of:

Signature of
witness: _____

Name of witness: _____

Address: _____

Occupation: _____

EXECUTED as a Deed
for and on behalf of
Freeline Therapeutics Limited
acting by a director

[**]

in the presence of:

Signature of witness: [**]

Name of witness: [**]

Address: [**]

Occupation: [**]

I, AMIT NATHWANI, of [**] have read, understand and accept the provisions of this Third Deed of Amendment and Termination and how it relates to my research and the AN Laboratory.

SIGNED _____ DATE: _____

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

IN WITNESS THIS DEED has been executed and delivered on the date appearing at the head of page 1.

EXECUTED as a Deed

For and on behalf of **UCL Business Ltd**

acting by a director) [**]
)
_____)
 [**]
 [**]

in the presence of:

Signature of witness: [**]

Name of witness: [**]

Address: [**]

Occupation: [**]

EXECUTED as a Deed

for and on behalf of

Freeline Therapeutics Limited

acting by a director

in the presence of:

Signature of witness:

Name of witness:

Address:

Occupation:

I, AMIT NATHWANI, of [**] have read, understand and accept the provisions of this Third Deed of Amendment and Termination and how it relates to my research and the AN Laboratory.

SIGNED [**]

DATE: 18/12/2019

DATED 10th April 2018

(1) FREELINE THERAPEUTICS LIMITED

-and-

(2) CELL THERAPY CATAPULT LIMITED

COLLABORATION AGREEMENT



Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

THIS COLLABORATION AGREEMENT (the “Agreement”) is dated 10 April 2018 (the “Effective Date”)

BETWEEN

- (1) **Freeline Therapeutics Limited** a company incorporated in England with company number 09500073 and whose registered office is at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts SG1 2FX (“**COLLABORATOR**”); and
- (2) **Cell Therapy Catapult Limited, trading as Cell and Gene Therapy Catapult**, a company incorporated and registered in England & Wales with company number 07964711 whose registered office is at 12th Floor Tower Wing, Guys Hospital, Great Maze Pond, London, SE1 9RT, United Kingdom (“**Catapult**”).

BACKGROUND

- (A) Catapult’s purpose in commissioning the cell and gene therapy manufacturing centre is to further its broader aims within the UK to develop novel technologies, processes, supply chains, facilities, skills, and working practices for simultaneous and cost effective large scale manufacture and distribution of multiple ATMP products.
- (B) COLLABORATOR is developing certain ATMP products. As part of this activity COLLABORATOR wishes to use the Centre in order to further develop and scale up manufacturing processes and capability for cell and gene therapy products.
- (C) COLLABORATOR and Catapult would each like to collaborate with the other as further set forth in this Agreement (“**Project**” or “**Collaboration**”, as further described in the work streams set out at **Schedule 1**). Other parties who collaborate with Catapult, and occupy space in the Centre will be referred to as “Collaborators”.
- (D) This document aims to record the contributions of each party with respect to this Agreement, and the terms under which COLLABORATOR and Catapult will work together within the Centre.

OPERATIVE PROVISIONS

1. DEFINITIONS AND INTERPRETATION

In this Agreement, the following words shall have the following meanings:

- | | |
|---|---|
| “Accompanied Access Areas” | the areas of the Centre marked yellow on the Plan which are accessible by any Collaborator, but on condition such access is in the company of Catapult personnel. |
| “Activity Related Inputs” | the inputs provided by Catapult as set out in Clause 9.2 and more specifically set out in Schedule 3 . |
| “Activity Related Input Contributions” | the non-refundable financial contribution made by COLLABORATOR with respect to the provision of the Activity Related Inputs, as specifically set out in Schedule 3 . |
| “Actual Occupation Date” | means the date by which Catapult has completed its obligations contained in this Agreement enabling COLLABORATOR to occupy the Module. |
| “Additional Inputs” | means Inputs COLLABORATOR requires Catapult to contribute to the Project, other than Activity Related Inputs and Integral Inputs, which will be arranged through the completion of an Additional Input Agreement in the form set out at Schedule 16 (“ Additional Input Agreement ”). |

“Additional Input Contributions”	the financial contribution made by COLLABORATOR with respect to the provision of any Additional Inputs requested from Catapult in the form set out at Schedule 16 (“ Additional Input Agreement ”).
“Affiliate”	In relation to a Party, means any person that Controls, is Controlled by, or is under common Control with that Party.
“Applicable Law”	any: <ul style="list-style-type: none">(a) statute, statutory instrument, by-law, order, regulation, directive, treaty, decree, decision of the European Council or law;(b) legally binding rule, policy, guidance or recommendation issued by any governmental, statutory or regulatory body with jurisdiction over this Agreement or the activities conducted hereunder; which relates to the performance of this Agreement and/or the inputs by the relevant party and/or the activities which are comprised in the Project; and(c) legally binding industry code of conduct or guideline.
“Background Intellectual Property”	<ul style="list-style-type: none">(a) In relation to COLLABORATOR, means the Intellectual Property that is either (i) owned by or licensed to COLLABORATOR prior to the Effective Date, or (ii) that is developed or licensed by COLLABORATOR after the Effective Date and outside of the conduct of activities for the Project; and in the case of either (i) or (ii), that COLLABORATOR uses in the performance of the Project, other than Foreground Intellectual Property; and(b) In relation to Catapult, means the Intellectual Property owned by or licensed to Catapult at the Effective Date, together with Intellectual Property that is developed by or licensed to Catapult after the Effective Date and outside of the conduct of activities for the Project; and in either case that Catapult uses in the performance of the Agreement, and that is not Foreground Intellectual Property. Catapult represents and warrants that to the best of Catapult’s knowledge and belief, as of the Effective Date, Catapult Background Intellectual Property, consists of the heads of Intellectual Property as set forth In the attached Schedule 4, which Catapult will update from time to time as additional Catapult Background Intellectual Property is brought into the Project.
“Business Rates”	means the portion of the business rates chargeable against the Centre paid for by COLLABORATOR in accordance with Clause 8.4.2 and the amount set out at Schedule 3 .
“Catapult Board”	means the directors of Cell Therapy Catapult Limited as registered at Companies House from time to time.

“Centre”	the Cell and Gene Therapy Catapult Manufacturing Centre located at Cell and Gene Therapy Catapult Manufacturing Centre, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, and edged blue on the Plans.
“CNC corridor”	means the controlled non-classified corridor forming part of the Common Access Areas and referred to in Schedule 12 .
“Code of Conduct”	the code of conduct set out at Schedule 5 .
“Commissioning”	has the meaning given in Clause 6.1 .
“Collaborator Forums”	means the Quality Forum, the Health and Safety Forum, and the Operational Forum, each as more particularly referenced, and described in Clause 9.6 and Schedule 15 .
“COLLABORATOR Personnel”	the employees, consultants or contractors of COLLABORATOR located at the Module or visiting the Module from time to time.
“COLLABORATOR Process”	means the process described in the Product Overview Document (or prior to this being in place, the Pre-Screen Questionnaire, as set out in Schedule 6) to be operated by COLLABORATOR under the Agreement in order to enable the production of COLLABORATOR Product on a large scale. It may be amended from time to time in accordance with Clause 7.2 and the QTA.
“COLLABORATOR Product”	the COLLABORATOR product, or products as defined in the QTA product list (or prior to this being in place, the Pre- Screen Questionnaire) to be produced through the use of the COLLABORATOR Process.
“COLLABORATOR Responsibilities”	the obligations on COLLABORATOR set out in Clause 10 (each one severally being a “ COLLABORATOR Responsibility ”).
“Common Access Areas”	any part of the Centre shown edged green on the Plan which does not form part of the Module, the Restricted Access Areas, or the Accompanied Access Areas, or that is designated by Catapult from time to time for common use by Catapult, COLLABORATOR, and other Collaborators in the Centre from time to time.
“Compensations”	has the meaning given to it in Clause 18.1 .
“Conducting Media”	any media for the transmission of Supplies.
“Confidential Information”	means any Information in any form or medium which is either disclosed by one Party or such Party’s Affiliates, or their legal counsel, advisors, contractors or consultants (“ the Disclosing Party ”) to the other Party or Its Affiliates, or their legal counsel, advisors, contractors or consultants (“ the Receiving Party ”), or to which either Party gains access as a result of: (a) COLLABORATOR’s occupancy of the Module and Centre; (b) Catapult or Third Party’s (to include any other collaborator) use of or access to the Centre at any time; or

(c) as a result of either Party's participation in any of the Collaborator Forums

concerning the business affairs, finances, technology, plans, strategy, products, manufacturing services, Know-how or services of (i) the Disclosing Party (ii) any of its Affiliates (iii) any other entity with which the Disclosing Party or any of its Affiliates is in business negotiations or has contracted or to which it owes a duty of confidence, or (iv) any other Collaborator ((iv) being an "Alternative Disclosing Party"), and all copies of the same.

"Control"

means (a) the direct or indirect ownership of fifty percent (50%) or more of the total voting power of securities or other evidences of ownership interest in a party or (b) the power to direct or cause the direction of the management and policies of such party, directly or indirectly, whether through ownership of voting securities, by contract or otherwise; and the terms "controlling" and "controlled" have meanings correlative to the foregoing, as the case may be.

"Disclosing Party"

has the meaning given in the definition of Confidential Information.

"Effective Date"

means the date as defined in the preamble of this Agreement.

"Establishment Inputs"

the inputs provided by Catapult as provided for in **Clause 9.3**.

"Establishment Input Contributions"

the non-refundable financial contributions payable in accordance with **Clause 8.4.5**, and set out in the Establishment Input Contributions Statement in **Schedule 6** to be made by COLLABORATOR with respect to the provision of the Establishment Inputs by Catapult.

"Expected Occupation Date"

1 July 2018, the contemplated date by which COLLABORATOR will occupy the Module, or such other earlier date as mutually agreed by the parties in writing.

"Facility Contribution"

the non-refundable financial contribution to be made by COLLABORATOR with respect to the provision of the Module and other capital aspects, as more particularly described at **Clause 8.4.1**, and at **Schedule 3**.

"Financial Contributions"

means the Activity Related Input Contributions, Integral Input Contributions, Establishment Input Contributions, the Facility Contributions, the Additional Input Contributions and/or any other contributions as agreed in writing between the Parties and provided by COLLABORATOR from time to time.

"Foreground Intellectual Property"

means the results, technical information, knowledge, inventions, improvements, experience, materials and data developed and arising directly from and as a direct result of the Project, together with any Intellectual Property in such items.

"GMP"

good manufacturing practice, being the standard required under Applicable Law.

"GMP Requirements"

the guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in the Commission 2003/94/EC, or as replaced by Directive 2017/1572 and/or Regulation 2017/1569 as appropriate and set out in Volume 4 of Eudralex (the rules governing medicinal products in the European Union), and the MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The Orange Guide).

“Health and Safety Forum”	means the forum in which COLLABORATOR, other Collaborators, and Catapult will convene to discuss health and safety matters as more particularly described in Schedule 15 .
“HVAC”	means heating, ventilation and air-conditioning.
“Improvement”	Means, with respect to any Intellectual Property or material: (a) all Improvements, modifications and/or adaptations of such Intellectual Property or materials and (b) all other Intellectual Property or in, derived from, relating to, or Interest which would Impair or restrict the use of, application, or rights comprised in, such Intellectual Property or material.
“Inputs”	the Activity Related Inputs, Integral inputs, Establishment Inputs and/or any other Inputs (“ Additional Inputs ”) as agreed in writing between the Parties and provided by Catapult to COLLABORATOR from time to time.
“Integral Input Contributions”	the non-refundable financial contribution made by COLLABORATOR with respect to the provision of the Integral Inputs, as more particularly described in Clause 8.4.4 , and at Schedule 3 .
“Integral Inputs”	the inputs provided by Catapult set out at Clause 9.1 .
“Insured Risks”	the risks covered by the policies of insurance under Clause 19.1 and 19.2 . In each case to the extent that cover is generally available on normal commercial terms in the UK insurance market at the time the insurance is taken out and any other risks against which Catapult reasonably insures from time to time, subject in all cases to any excesses, limitations and exclusions imposed by the insurers.
“Intellectual Property”	any and all issued patents and patent applications, inventions, utility models, registered and unregistered trademarks and service marks, registered designs, unregistered design rights, domain names, trade or business names, copyright, database rights, rights in respect of confidential information, rights under data exclusivity laws, rights under licences, rights under orphan drug laws, property rights in biological or chemical materials, topography rights, Know-how, extension of the terms of any such rights (Including supplementary protection certificates), applications for and the right to apply any of the foregoing registered property and rights, and similar or analogous rights anywhere in the world.
“IT Infrastructure”	the information technology facilities in the Centre for use by COLLABORATOR and, where applicable, by other Collaborators as more particularly described in Schedule 10 .
“Know-how”	unpatented technical information (including without limitation information relating to inventions, discoveries, concepts, methodologies, models, research, development, and testing procedures; the results of experiments, tests, and trials; manufacturing processes, techniques, and specifications; and quality control data, analyses, reports, and submissions) that is not in the public domain.

“Lease”	a lease dated 1 October 2015 made between the (1) Stevenage Bioscience Catalyst and (2) Cell Therapy Catapult Limited.
“Liability”	liability arising out of this Agreement, whether in contract, tort, misrepresentation, restitution, under statute or otherwise, including any liability under an indemnity contained in this Agreement,
“Licence Period”	means the Term.
“MAL”	means material airlock.
“Manufacturing Office”	the manufacturing office space forming part of the Module, allocated for COLLABORATOR’s use in accordance with Clause 3 , and more particularly described in Schedule 12 .
“Manufacturing Space”	the manufacturing space forming part of the Module, allocated for COLLABORATOR’s use in accordance with Clause 3 , more particularly described in Schedule 12 .
“Module”	the specific Manufacturing Space, Manufacturing Office, and Non-Manufacturing Office each allocated by Catapult under this Agreement for COLLABORATOR’s occupation and use at the Centre for carrying out the Project shown edged in red on the Plan, and which shall include all fixtures and fittings and plant and machinery set out in the Schedule of Condition and Inventory of Module Fixtures and Fittings at Schedule 7 .
“Necessary Consents”	all planning permissions and all other consents, licences, permissions, certificates, authorisations and approvals whether of a public or private nature which shall be required by any regulatory authority for performance of Project.
“Non-Manufacturing Office”	means the office space allocated for COLLABORATOR’s use in Clause 3 , forming part of the Module, the specifications for which are set out in Schedule 12 .
“On-boarding”	part of the Establishment inputs and a process completed by Catapult together with COLLABORATOR involving the risk assessment and regulatory oversight required for the On-boarding Project as referred to in Clause 9.3.1(b) , and more particularly set out at Schedule 6 .
“On-boarding Project”	the establishment of COLLABORATOR’s Process and Product at the Centre in accordance with the process described in Schedule 6 .
“Operational Forum”	means the forum in which COLLABORATOR, other Collaborators, and Catapult will convene to discuss operations matters connected with the Centre as more particularly described in Schedule 15 .
“PAL”	means personnel airlock.
“Parties”	COLLABORATOR and Catapult; “ Party ” shall mean either of them, and “ Parties ” shall mean both COLLABORATOR and Catapult.
“Permitted Use”	activity strictly in connection with the performance of the Project.
“PrAL”	means product airlock.

“Product Overview Document” or “POD”	means a quality document completed as part of the On-boarding Project defining the COLLABORATOR Process and Product.
“Plans”	the plans of the Module allocated to COLLABORATOR under this Agreement, and of the Centre generally, attached to this Agreement at Schedule 2, Part 4 .
“Process Transfer”	means an Establishment Input, and the practical transfer of COLLABORATOR’S equipment and processes into the Centre under the control and responsibility of COLLABORATOR as referred to in Clause 9.3.1 and more particularly set out at Schedule 6 .
“Project”	means the workstreams set out In Schedule 1 .
“Quality Forum”	means the forum in which COLLABORATOR, other Collaborators, and Catapult will convene to discuss quality matters connected with the Centre as more particularly described in Schedule 15 .
“Quality Management System”	a collection of business processes and governance structures focused on consistently meeting Regulatory Authority and GMP requirements. The Quality Management System is expressed as an organisational structure, policies, procedures, processes and resources needed to maintain compliance to Eudralex Vol 4, Chapter 1 that are set out In the Quality Technical Agreement.
“Quality Technical Agreement” or “QTA”	the agreement governing the quality aspects of the Centre that are comprised in the Quality Management System.
“Quarter”	a period of three months commencing on 1 January, 1 April, 1 July, or 1 October; and “Quarterly” shall be construed accordingly.
“Receiving Party”	has the meaning given in the definition of Confidential Information.
“Registered Rights”	patents, registrable design rights, trademarks, and all other registered Intellectual Property.
“Regulatory Authority”	the competent authority for each country or for any relevant grouping of countries legally responsible for authorising the manufacture, clinical trials or the sale or supply of human pharmaceutical products in that country or group of countries.
“Restricted Access Area(s)”	the parts of the Centre accessible only by Catapult personnel marked Pink on the Plan.
“Service Level Commitments”	the service delivery principles set out at Schedule 15 .
“Shared Restricted Access Area”	means the areas shared between the Manufacturing Space and an adjacent manufacturing space belonging to another Collaborator marked in turquoise on the Plans.
“Steering Committee”	the representatives of the COLLABORATOR and Catapult appointed as set out in Clause 9.5 .
“Supplies”	water, gas, air, foul and surface water, drainage, electricity, oil, telephone, heating, telecommunications, internet, data communications and similar supplies or utilities.

“Technology Transfer”	the transfer of COLLABORATOR’s existing production and/or manufacturing processes into the Module by COLLABORATOR.
“Term”	the period specified in Clause 17.1
“Termination Date”	the date on which this Agreement expires or terminates for any reason.
“Third Party”	any person other than a Party or its Affiliates.
“UPS”	uninterrupted power supply.
“Validation”	the action of proving, in accordance with the principles of Good Manufacturing Practice (Eudralex Volume 4, Annex 15), that any GMP process functions in accordance with predefined requirements, is robust and reproducible.
“Warehouse and Procurement Management Provisions”	the standards and obligations relating to the management of the warehouse set out at Schedule 8 .
“Warehouse Space”	the warehouse space allocated for COLLABORATOR’s use in accordance with Clause 3 and Schedule 8 , and more particularly described in Schedule 12 .
“Year”	means the financial year ending 31 March.

1.1 In this Agreement, unless otherwise specified:

- 1.1.1 references to Clauses and Schedules are to the clauses of, and schedules to, this Agreement;
- 1.1.2 headings are for convenience only and do not affect the interpretation of this Agreement;
- 1.1.3 references to a person includes a body corporate or unincorporated body, and references to a company includes any company, corporation or other body corporate, wherever and however incorporated or established;
- 1.1.4 unless the context otherwise requires, words in the singular shall include the plural and vice versa;
- 1.1.5 references to approvals or notices being “in writing” or “written” shall include email;
- 1.1.6 any reference to a statute or statutory provision is a reference to it as amended, extended, re-enacted and/or replaced from time to time; and
- 1.1.7 ‘Including’ means ‘Including but not limited to’ and ‘include’ and ‘includes’ shall be construed accordingly.

2. CONDUCT OF THE PROJECT

The Parties will undertake the Project in accordance with the provisions of this Agreement.

3. OCCUPATION OF THE MODULE AND THE WAREHOUSE SPACE

- 3.1 Catapult permits COLLABORATOR to occupy the Module on the terms set out in **Schedule 2**.
- 3.2 Catapult permits COLLABORATOR to access and use the Warehouse Space in accordance with the terms in **Schedule 8**.

4. MODULE SPECIFICATION

- 4.1 Catapult will ensure the Manufacturing Space will be in accordance with the specifications at **Schedule 12 Part A** and will at all times comply with Applicable Laws (including GMP Requirements).
- 4.2 Catapult will ensure the Manufacturing Office and Non-Manufacturing Office will be in accordance with the specifications at **Schedule 12 Part B**.
- 4.3 Catapult will also ensure that use of the Shared Restricted Access Areas and Warehouse Space will at all times comply with Applicable Laws including EU-GMP Requirements, in relation to any collaborator other than COLLABORATOR.

5. CENTRE SPECIFICATIONS

The Centre will be a UK-licensed EU-GMP-compliant facility developed In close relationship with the Medicines and Healthcare Products Regulatory Agency comprising the facilities and services set out at **Schedule 12, Part C**. Catapult will also ensure that it has In place all consents and licenses required for operation of the Facility.

6. COMMISSIONING AND QUALIFICATION OF THE CENTRE

- 6.1 In advance of COLLABORATOR being granted access to the Manufacturing Space and subject to **Clause 7**, Catapult will test equipment, facilities and/or plant which is Catapult owned, or rented by Catapult and installed, (and following grant of access, test all Catapult owned or rented equipment, facilities and/or plant which is subsequently installed or up-graded) In order to verify it functions according to its design objectives or specifications ("**Commissioning**").
- 6.2 Commissioning will not cover the formal qualification of manufacturing systems or manufacturing process equipment but will include the static and dynamic commissioning of the following by Catapult:
 - 6.2.1 the Building Management System (BMS);
 - 6.2.2 the electrical supply (single and three phase);
 - 6.2.3 the boilers;
 - 6.2.4 the chiller;
 - 6.2.5 HVAC;
 - 6.2.6 Quality Control area HVAC;
 - 6.2.7 lighting – including emergency lighting;
 - 6.2.8 back-up generator;
 - 6.2.9 UPS systems;
 - 6.2.10 door interlocks;
 - 6.2.11 pharmaceutical grade gas supplies (air, oxygen, carbon dioxide and nitrogen)
 - 6.2.12 CCTV
 - 6.2.13 fire alarm
 - 6.2.14 LN2 / Low level, temperature and oxygen monitors;
 - 6.2.15 drainage; and
 - 6.2.16 appropriate IT Infrastructure (including cable network, switches, and server rooms).

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 6.3 Where appropriate, Catapult will qualify the building, systems and equipment that form part of the Centre, and this will extend to installation qualification, operational qualification, and performance qualification of all GMP direct impacting systems and integral equipment. Any software related to GMP direct impacting systems and integral equipment at the Centre will be Validated by Catapult and will comply with EU GMP Annex 11.
- 6.4 Formal qualification will be undertaken (which includes installation qualification (IQ) and operational qualification (OQ)) concurrent with leveraging the output of Centre commissioning, performance qualification (PQ), which will only occur subsequent to the completion of commissioning, IQ and OQ, PQ will only be applied to those services, systems and items of equipment that have been identified as having direct impact on product quality according to a formal system level impact assessment. These include:
- 6.4.1 Manufacturing Space and all additional air locks HVAC;
 - 6.4.2 Warehouse HVAC;
 - 6.4.3 Grade C corridor and technical area HVAC;
 - 6.4.4 Carbon dioxide system;
 - 6.4.5 Nitrogen gas system;
 - 6.4.6 Liquid nitrogen system, storage tanks (PQ will be carried out on conjunction with a collaborator) and shared Controlled Rate Freezing equipment (COLLABORATOR will be responsible for their own cycle development and PQ);
 - 6.4.7 Oxygen system;
 - 6.4.8 Cold room, fridges, freezers (PQ will be carried out in conjunction with COLLABORATOR);
 - 6.4.9 the Environmental Monitoring System (EMS) (e.g. viable air sampler, non-viable particulate monitors); and
 - 6.4.10 Environmental monitoring equipment, PQ will be carried out in conjunction with COLLABORATOR.

7. PROCESS AND PRODUCT

7.1 VALIDATION

Process validation and transfer of the COLLABORATOR Process into Module is entirely the responsibility of COLLABORATOR.

7.2 PROCESS AND PRODUCT AMENDMENT

- 7.2.1 Catapult confirms that it approved the information contained in the initial POD provided as part of the On-boarding Project as describing the COLLABORATOR Process and COLLABORATOR Product that can and may be developed, implemented, and manufactured in the Module by COLLABORATOR. The initial COLLABORATOR Product provided as part of the On-boarding Project has been included in the QTA Product List, and, therefore, constitutes a COLLABORATOR Product. It further confirms that such approval of COLLABORATOR Product will remain valid during the Term on the condition that no amendments are made at a later stage.
- 7.2.2 The COLLABORATOR Product and Process will be again vetted and approved in advance of occupation as part of the On-boarding Project. In the event the On-boarding Project reveals any variations and/or additions to the information contained in the POD (“**Product or Process Modifications**”) these will be managed as changes in accordance with **Clause 7.2.4**.

- 7.2.3 Product or Process Modifications will be considered in accordance with the following procedure:
- (a) COLLABORATOR must notify Catapult in writing of its application for the intended changes (the “Notification”); and
 - (b) In response, Catapult will apply the criteria set out in **Clause 7.2.4**. If the requested Product or Process Modifications meet the requirements of these steps, and are therefore capable of Introduction, Catapult will always endeavour to approve the earliest date feasible for introduction, allowing for logistical constraints, and the competing interests of other Collaborators in existence at the time of request (the “Introduction Date”),
 - (c) Catapult will confirm the outcome of the application of the criteria in **Clause 7.2.4** and, if applicable, of the Introduction Date in writing to COLLABORATOR as soon as it is able to from the date of notification under **Clause 7.2.3(a)** but in any event within 30 calendar days of receipt of Notification by Catapult. Where Catapult indicates that the Modifications will not be permitted, it will identify the reasons why such Notification has been refused.
- 7.2.4 Catapult will permit a new COLLABORATOR Product(s), and/or COLLABORATOR Process(es) or COLLABORATOR modification to such COLLABORATOR Product or COLLABORATOR Process if:
- (a) the new or modified COLLABORATOR Product(s), and/or COLLABORATOR Process(es) meet the requirements of the QTA;
 - (b) the proposed product is not a restricted product listed at **Clause 7.3**;
 - (c) it does not impact on Catapult’s Inputs or the operation of the Centre and as a result materially affect Catapult’s ability to comply with GMP or GMP Requirements;
 - (d) it does not inherently compromise the safety of the Centre, or that of any other collaborator;
 - (e) it does not place an additional, unreasonable demand on the resources of Catapult personnel and their ability to operate the Centre;
 - (f) it does not interfere with the Catapult’s, or any other Collaborator’s compliance with their respective legal duties; and/or
 - (g) it can be accommodated in the Centre, taking into account the overall capacity of the Centre.
- 7.2.5 In the event that COLLABORATOR does not agree with the outcome of Catapult’s application of the principles under **Clause 7.2.4**, the matter will be referred to the Steering Committee for resolution, and If no agreement is reached within a reasonable period, then the Parties will comply with the Expert Determination Procedure set out in **Schedule 13**.

7.3 RESTRICTED PRODUCTS

COLLABORATOR will not be permitted, and Catapult undertakes that it will not allow any other Collaborator to produce or utilise in their process the following products in the Centre (unless prior agreement is sought from all collaborators by Catapult):

- 7.3.1 B Lactam Antibiotics;
- 7.3.2 Other highly sensitising antibiotics;
- 7.3.3 Pathogenic Organisms (Containment Level 3 or 4);
- 7.3.4 GMO 3 and above;

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- 7.3.5 Radiopharmaceuticals;
- 7.3.6 Ectoparasiticides; or
- 7.3.7 Sources of ionising radiation (but excluding low energy laboratory scale X-irradiators which have been assessed and approved by Catapult).

8. FINANCIAL CONTRIBUTIONS

- 8.1 A risk and capital contribution will be charged throughout the Term calculated at the rate of [**] of each Financial Contribution, except for the Facility Contribution and Business Rates. The risk and capital contribution will remain fixed at the rate of [**] throughout the Term.
- 8.2 VAT, if applicable, will be added to all Financial Contributions.
- 8.3 Any changes to the Financial Contributions (other than the Facility Contributions which are fixed for the Term) will be made once per year based on the new annual budget which will be discussed at the Operational Forum.
- 8.4 COLLABORATOR will make the following Financial Contributions to the costs of the Collaboration:
 - 8.4.1 subject to **Clauses 8.2 and 8.3**, from the Actual Occupation Date, for each Module occupied by COLLABORATOR, the Facility Contribution, payable quarterly in advance;
 - 8.4.2 subject to **Clauses 8.1 to 8.3**, from the Actual Occupation Date, for each Module occupied by COLLABORATOR, one-fifth of the total costs chargeable against Centre in the form of Business Rates, payable quarterly in advance;
 - 8.4.3 the Activity Related Input Contributions as they are incurred, due Individually from COLLABORATOR and within 30 days of receipt of invoice;
 - 8.4.4 subject to **Clauses 8.1 to 8.3**, from the Actual Occupation Date, the Integral input Contributions payable quarterly in advance and calculated in accordance with the following provisions of **Clauses 8.4.4(a) and (b)**:
 - (a) Catapult will estimate the aggregate Integral Input Contributions Incurred for 5 Modules in concurrent occupation for any 1 year (the “**Estimated Aggregate Integral Input Contributions**”), COLLABORATOR will be responsible for a fixed amount, as set out at Schedule 3, such amount to be based on a [**] share of this Estimated Aggregate Integral Input Contributions. When 5 Modules are in concurrent occupation (“Full Occupation”), the contributions model in **Clause 8.4.4(b)** will apply.
 - (b) From the date Full Occupation is achieved, COLLABORATOR will continue to pay a [**] share of the Estimated Aggregate Integral Input Contributions Incurred, However, from and including the first anniversary date (the “**First Anniversary Date**”) that Full Occupation is achieved, a reconciliation will take place at the end of each Year and a refund will be made to or further contribution will be received from COLLABORATOR with respect to its share of the Integral Input Contributions based on the difference between the Estimated Aggregate Integral Input Contributions, and the pro rata actual aggregate Integral Input Contributions incurred for that Year. Reconciliation will be based on audited accounts,
 - 8.4.5 the Establishment Input Contributions will be payable directly to Catapult as they are incurred on COLLABORATOR’S behalf and following receipt of invoice; and
 - 8.4.6 Save as otherwise provided all contributions payable by COLLABORATOR to Catapult pursuant to this Agreement will be payable within 30 days of receipt of an accurate, complete and valid VAT invoice by COLLABORATOR for such costs.
- 8.5 Catapult will use reasonable endeavours to ensure the Actual Occupation Date is not later than the Expected Occupation Date, In the event the Actual Occupation Date is not achieved by the Expected Occupation Date, then Facility Contributions, Business Rates and Integral Input Contributions will only accrue on a pro rata basis from the Actual Occupation Date. In the event COLLABORATOR wishes to

occupy the Module before the Expected Occupation Date It will notify Catapult of its requested Expected Occupation Date not less than 90 days' In advance of the date It wishes to occupy the Module, Entry on such revised Expected Occupation Date will be subject to Catapult consent (not to be unreasonably withheld; however, for clarity, it will be reasonable to withhold consent if Catapult will not be able to complete Its obligations In order to enable occupation of the Module, in accordance with the definition of the "Actual Occupation Date" by the date requested by COLLABORATOR). However in the event COLLABORATOR wishes to delay its occupation to after the Expected Occupation Date, it will remain liable to pay all Contributions from the Expected Occupation Date.

- 8.6 By being part of the Centre, COLLABORATOR has access to the wider Catapult supporting infrastructure which includes, but is not limited to, reimbursement support, clinical trial support, process development capability, and regulatory and market access consultancy expertise, The cost of such Additional Inputs are to be agreed through separate negotiation and contractual agreement.
- 8.7 Catapult undertakes to keep full and proper books of account and records relating to the Integral Input Contributions and the Establishment Input Contributions. In addition COLLABORATOR will be provided with the opportunity to comment on such planned expenditure and consensus sought through participation in the Collaborator Forums (although for clarity, Catapult reserves its discretion in exercising its professional Judgment In relation to making any final decisions with respect to the Integral Input Contributions, Activity Related Input Contributions and Establishment Input Contributions incurred, while being consistent with the objectives set out in the terms of reference for the Collaborator Forums, particularly with respect to maintaining a suitable level of services required for robust operation of a licensed facility suitable for late stage clinical and commercial manufacture of ATMPs in the most economical way).
- 8.8 At the beginning of each Year during the Term Catapult will provide to all Collaborators a budget setting out all anticipated contributions for the Year with respect to Integral and Activity Related Inputs to be provided in that Year. In addition to this, from the date Full Occupation is achieved, a quarterly statement will be provided to all Collaborators in the Centre comparing actuals to the budgeted amounts.
- 8.9 Catapult will procure an audit for each Year during the Term to be carried out by an Independent auditor acceptable to all Collaborators. The Audit report will be made available to all Collaborators in the Centre.
- 8.10 In the event that an MHRA MIA (IMP) license or any other consent required for operation of the Centre by Catapult In accordance with GMP or Applicable Laws is not granted to Catapult on or before the Expected Occupation Date, then the Facility Contribution and Integral Input Contribution will be reduced [**] until the date that an MHRA MIA (IMP) license is granted. Catapult will also waive any additional [**] as a result of any such delay in establishing GMP compliance. For the avoidance of doubt, COLLABORATOR will remain liable for [**]
- 8.11 In recognition of the collaboration required to achieve an MHRA license, In the event COLLABORATOR elects to occupy the Module after the Actual Occupation Date, the revised deadline for an MHRA MIA (IMP) licence or Necessary Consent to be granted, will be delayed by a period of time equal to the number of days between the Actual Occupation Date and the subsequent later date that COLLABORATOR actually occupies the Module.
- 8.12 Catapult will use best efforts, in line with commercial practice, to minimise facility downtime and to plan any such downtime so as to minimise business impact for COLLABORATOR. Catapult will use best efforts to ensure [**]

[**]

[**]

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i. [**]

[**]

[**]

[**]

[**]

In any event of conflict between this Clause 8.12 of this Agreement and the QTA, the QTA shall prevail.

9. CATAPULT INPUTS, FACILITIES AND SUPPORT

The operation of the Centre is dependent on a range of critical inputs split between:

- (a) **Integral Inputs** which are Inputs Catapult, using its reasonable judgment considers as fundamental to the operation of the Centre and that all collaborators will draw on in equal measure. Such Integral Inputs are listed in **Clause 9.1**, but may be varied from time to time by Catapult, in good faith, to cater for the common, but not necessarily universal, requirements of the collaborators in the Centre, while at all times maintaining robust compliance with health and safety and GMP guidelines; inputs included at **Clause 9.1** may not be removed or varied without prior notification of COLLABORATOR, and
- (b) **Activity Related Inputs** which are inputs that are dependent on COLLABORATOR's manufacturing processes and activity, and are listed at **Clause 9.2** but may be varied from time to time by Catapult, in good faith, to meet COLLABORATOR'S requirements and with prior notification of COLLABORATOR, but may not include Items from **Clause 9.1** without prior agreement of COLLABORATOR.
- (c) **Establishment inputs** which are activities to be performed by Catapult, in conjunction with COLLABORATOR, to support the On-boarding Project.

It is a condition of occupation that the Integral Inputs, Establishment Inputs, and Activity Related Inputs will be procured through Catapult.

- (d) **Additional Inputs** are inputs COLLABORATOR requires Catapult to contribute to the Project, that are not Integral Inputs, Establishment Inputs or Activity Related Inputs. These will be arranged through the completion and execution of an Additional Input Agreement, on reasonable terms to be agreed, in the form set out at **Schedule 16** ("**Additional Input Agreement**"). Once signed by both Parties, the Additional Input Agreement will amend this agreement and an Additional Input will be deemed appended to the list of Additional Inputs at **Clause 9.4** and any associated contributions from COLLABORATOR in consideration of the Additional Inputs will be included in the Additional Input Agreement, and inserted at **Schedule 3**. For the avoidance of doubt, such an Input which does not impact on the Centre, the Centre's GMP compliance or other Collaborators may, alternatively where COLLABORATOR determines, be sourced by COLLABORATOR from a Third Party provider, Which will be reasonably facilitated by Catapult, where requested by COLLABORATOR.

- 9.1 Catapult shall provide the following Integral Inputs:
- 9.1.1 the Quality Management System and supporting quality assurance function assuring all GMP inputs contributed by Catapult are maintained in compliance with GMP Requirements;
 - 9.1.2 management and governance of the Quality Management System GMP compliance process;
 - 9.1.3 regulatory compliance of the Centre from start up, including handling of associated MHRA compliant activities such as routine audits; for the avoidance of doubt all audit of COLLABORATOR Process will be COLLABORATOR'S responsibility;
 - 9.1.4 Catapult and Centre insurance as described in **Clause 19**;
 - 9.1.5 safety systems and equipment such as emergency light testing, fire extinguishers, health and safety equipment outside the Manufacturing Space, and associated safety audits;
 - 9.1.6 a managed reception during business hours, and the provision of a mechanism for COLLABORATOR to access the Module at any time (24 hours a day, 7 days a week, 365 days per year), except in situations of Centre shutdown / an emergency;
 - 9.1.7 all utilities necessary for the operations of the Centre (but not the Manufacturing Space) as set out in **Schedule 14**;
 - 9.1.8 support for IT Infrastructure. For the avoidance of doubt, this does not include applications support for COLLABORATOR;
 - 9.1.9 hosting, maintenance and administration of all IT systems (BMS, EMS, eQMS, LIMS and WMS) plus all required access rights for IT systems required primarily for Centre functions and required even when no collaborators are in occupation (BMS, EMS);
 - 9.1.10 receipt of incoming materials into the Centre within business hours;
 - 9.1.11 a system for booking in and managing short term storage of COLLABORATOR'S inventory for raw materials, consumables, product contact materials and excipients within the warehouse;
 - 9.1.12 short term storage of COLLABORATOR Products (including starting materials, intermediates, active substances, and final product thereof) subject to terms to be agreed;
 - 9.1.13 out of hours call out system for all facilities alarms (bar the Manufacturing Space alarms);
 - 9.1.14 scheduled cleaning and disinfection of all areas outside of the Manufacturing Space and outside of any Quality Control laboratory space occupied by any collaborator;
 - 9.1.15 (save with respect to the Manufacturing Space which is provided for in **Clause 9.2.1** and for any Quality Control laboratory space occupied by any collaborator) perform environmental monitoring in the form of viable and non-viable particulate monitoring In the Centre required to demonstrate maintenance of the appropriate environmental classifications;
 - 9.1.16 access to a controlled rate freezer and allocated storage capacity of released starting materials and quarantined drug substance or drug product at the following temperatures; controlled room temperature, 2-8°C, -20°C, -80°C and gas phase of liquid nitrogen;
 - 9.1.17 COLLABORATOR relationship management, including via the Steering Committee;
 - 9.1.18 a kitchen area and vending machines for snacks, hot and cold drinks within the Centre;
 - 9.1.19 a dedicated secure Manufacturing Office and Non-Manufacturing Office per Module;
 - 9.1.20 routine calibration, maintenance, requalification of facilities and equipment listed in **Clause 6.3**, as appropriate for their function;

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- 9.1.21 access to a fair share of communal general refuse disposal facilities, for use by Catapult, COLLABORATOR and other Collaborators;
- 9.1.22 on request by COLLABORATOR, from time to time, Catapult shall provide general information on the Centre, equipment at the Centre, and general consumables, or as otherwise reasonably required in relation to the Centre or Module, for regulatory purposes or in relation to any investigation or inspection by any Regulatory Authority. The Catapult reserves the right to provide an Additional Input Statement for any such requests that will incur input from the Catapult above and beyond that expected during routine operation and;
- 9.1.23 If COLLABORATOR is the subject of any inspection or investigation by any Regulatory Authority, Catapult shall provide COLLABORATOR with all reasonable assistance, and, at COLLABORATOR's request and expense, or as required by any Regulatory Authority, be present for any inspection of the Module by any Regulatory Authority.

9.2 Catapult shall provide the following Activity Related Inputs:

- 9.2.1 perform environmental monitoring in the form of viable monitoring and non-viable particulate monitoring required to demonstrate maintenance of the appropriate environmental classifications, including undertaking remote non-viable sampling in the Manufacturing Space. The COLLABORATOR is responsible for performing viable sampling in the Manufacturing Space which will then be processed by Catapult;
- 9.2.2 supply of measured electrical power, and all other necessary utilities, to the Manufacturing Space;
- 9.2.3 routine maintenance for the air handling system, including ULPA and HEPA filter changes
- 9.2.4 gowning for Catapult staff providing services to the collaborators, (COLLABORATOR gowning is ordered from Catapult warehouse stock);
- 9.2.5 provision of QA inputs to support COLLABORATOR activity within the module, in terms of handling non-process related deviations, Quality Events and planned changes, cleanroom environmental excursions, governance of Catapult generated GMP data provided to COLLABORATOR, providing GMP documentation to support QP certification of Drug Product;
- 9.2.6 Leased telephone line with a data package from the supplier if required;
- 9.2.7 Manufacturing Space decontamination on request from COLLABORATOR;
- 9.2.8 a measured supply of pharma grade oxygen, nitrogen, carbon dioxide, and compressed air;
- 9.2.9 transfer of decontaminated clinical, biological and hazardous chemical liquid waste from the liquid waste storage area and arrange its removal from the Centre by appropriately licensed contractors. The procedure for decontamination and disposal of are volume viral-contaminated waste will be defined between Catapult and COLLABORATOR;
- 9.2.10 packing and dispatch as described in **Schedule 8**;
- 9.2.11 access rights to IT systems required for COLLABORATOR activity within the module: eQMS, LIMS, WMS;
- 9.2.12 additional IT support if agreed in writing by the Parties (subject to request, and availability at the time of request);
- 9.2.13 a stand-by facility to receive incoming materials into the Centre outside of business hours;
- 9.2.14 Quality Assurance support for COLLABORATOR operation within the Module; and
- 9.2.15 Engineering and maintenance support for COLLABORATOR operation within the Module.

9.3 Catapult shall provide the following Establishment inputs:

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- 9.3.1 Catapult will work in cooperation with COLLABORATOR to define and implement an agreed strategy for Technology Transfer, made up of;
- (a) Process Transfer; defining, implementing and/or supporting conduct of Process Transfer, but such process under the control and responsibility of COLLABORATOR, and
- (b) On-Boarding; defining, and implementing conduct of On-Boarding in collaboration with COLLABORATOR, but such process under the control and responsibility of the Catapult and described in **Schedule 6**.
- 9.3.2 Catapult *will* clean and decontaminate the Manufacturing Space and ensure the Manufacturing Space is operating at the specified cleanliness grade prior to COLLABORATOR occupation.
- 9.3.3 With respect to Collaborators, other than COLLABORATOR, Catapult will select and authorise all such Collaborators and ensure their processes and procedures meet the minimum standards required by Catapult.

9.4 Catapult shall provide the following Additional Inputs;

Additional Inputs are Catapult activities requested by COLLABORATOR (acting In Its sole discretion) because of a project identified need that are incorporated into this Agreement through the execution by both Parties of an Additional Input Agreement in accordance with **Clause 9(d)** above.

9.5 Steering Committee

The Parties will each nominate two representatives who will form the steering committee for the Project (“**Steering Committee**”). Where possible the representatives from both Parties will be the same as those serving on the steering committee for the On-boarding Project. The Steering Committee will meet (by telephone or in person) as required to discuss matters relating specifically to the COLLABORATOR and/or the Project (such as changes to Contributions and inputs, staffing updates, collaboration performance and resolution of issues). The Steering Committee will also participate in dispute resolution as set out In **Clause 33** as required.

9.6 Collaborator Forums

Catapult undertakes to COLLABORATOR that it will ensure that the Collaborator Forums take place in accordance with the frequencies, the parameters, and all other terms set out in **Schedule 16**.

9.7 Catapult Staff

Catapult will ensure that all Catapult staff and third parties who are engaged by Catapult to provide the inputs set out in Clause 9 are appropriately skilled and trained.

10. COLLABORATOR RESPONSIBILITIES

10.1 COLLABORATOR shall, and shall ensure that COLLABORATOR Personnel shall, comply with the following COLLABORATOR Responsibilities;

- 10.1.1 abide by the Code of Conduct and all other reasonable guidelines and protocols in force from time to time at the Centre;
- 10.1.2 handle all large volume liquid waste (such as culture media and buffers) within the Manufacturing Space and securely and safely transfer it to the handling area in the Centre (as designated by Catapult from time to time);
- 10.1.3 collect all small volume liquid waste in a sealable container within the Manufacturing Space and decontaminate it in-situ before removing it from the cleanroom via the MAL out to a waste staging and disposal area;
- 10.1.4 remove all solid waste from the cleanroom via the MAL out to a staging area for removal);
- 10.1.5 maintain and implement in accordance with Catapult’s standard operating procedures cleaning regimes for the Manufacturing Space;

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- 10.1.6 unless otherwise agreed with Catapult, define and implement Process Transfer;
 - 10.1.7 perform as required by Catapult all appropriate environmental monitoring within the Manufacturing Space and make the plates available to Catapult for analysis;
 - 10.1.8 obtain, and maintain insurance for COLLABORATOR in accordance with Clause 19; and
 - 10.1.9 comply with its obligations under the QTA.
- 10.2 If Catapult's performance of its obligations under this Agreement is prevented or delayed by any act or omission of COLLABORATOR, its agents, contractors, sub-contractors or employees, Catapult shall not be liable for any costs, charges or loss sustained or incurred by COLLABORATOR arising directly from such prevention or delay.
- 10.3 if COLLABORATOR delays or does not perform its obligations set out in **Clauses 10.1.1, 10.1.2, 10.1.3, 10.1.4, 10.1.5, 10.1.7 and 10.1.9** above, Catapult may perform such obligations in its place. COLLABORATOR will reimburse Catapult for any reasonable out-of-pocket costs (as evidenced by appropriate invoices) that it incurs in discharging such obligations on COLLABORATOR'S behalf (for clarity, "**obligations**" as used in this clause Includes other terms commonly used synonymously with the term "**obligation**", An example is "responsibility" as used in this **Clause 10**).

11. BACKGROUND INTELLECTUAL PROPERTY

- 11.1 Subject to the provisions of this Agreement, COLLABORATOR hereby grants to Catapult a non-exclusive, fully paid-up, royalty-free, licence, under COLLABORATOR'S Background Intellectual Property to undertake the Project with COLLABORATOR during the Term.
- 11.2 Subject to the provisions of this Agreement, Catapult hereby grants to COLLABORATOR a non-exclusive, fully paid-up, sub-licensable, royalty-free, licence, under Catapult's Background intellectual Property to undertake the Project and exploit COLLABORATOR'S Foreground Intellectual Property during the Term,
- 11.3 From the Termination Date, such license in **Clause 11.2** will extend to permit COLLABORATOR to replicate the Module, and to such extent as required to enable COLLABORATOR to otherwise replicate, utilise and develop the COLLABORATOR Process, and/or to produce and exploit the COLLABORATOR Product and COLLABORATOR Foreground Intellectual Property, provided it is acknowledged that COLLABORATOR, at its own cost, will need to procure the consents required to use any Third Party's Intellectual Property Including but not necessarily limited to any such Third Party Intellectual Property forming any part of the following Items that constitute the overall Catapult Background Intellectual Property when Catapult Background Intellectual Property is used by COLLABORATOR outside the Centre or from the Termination Date: the Electronic Quality Management System, the Laboratory Information Management System, Warehouse Management System and Environmental Monitoring System. It is acknowledged that, following termination or expiry of the Agreement, Catapult cannot procure the grant of such rights and that if COLLABORATOR does not procure such rights that Catapult accepts no liability whatsoever for claims resulting from breaches of any Third Party's Intellectual Property resulting from COLLABORATOR'S use of the relevant Catapult Background Intellectual Property without a licence to the necessary Third Party's Intellectual Property.
- 11.4 This Agreement does not affect the ownership of any Intellectual Property in any Background Intellectual Property or materials of a Party. Each Party will retain the sole and exclusive ownership rights in and to Its Background Intellectual Property and except for the license granted to Catapult in **Clause 11.1** and to COLLABORATOR in **Clause 11.2** and **Clause 11.3**, nothing in this Clause 11 will be construed as giving to either Party any rights to use any Background Intellectual Property of the other Party other than as expressly granted by this Agreement. Each Party will treat the other Party's Background Intellectual Property as Confidential Information belonging to that other Party.

12. FOREGROUND INTELLECTUAL PROPERTY

- 12.1 All Foreground Intellectual Property excluding Catapult Foreground Intellectual Property (as defined in **Clause 12.2** below), whether it is capable of being a Registered Right or not, shall be deemed to be the sole property of COLLABORATOR, regardless of which Party created such Foreground Intellectual Property ("**COLLABORATOR Foreground Intellectual Property**"). COLLABORATOR Foreground Intellectual Property shall constitute Confidential information belonging to COLLABORATOR. COLLABORATOR may take such steps as it may decide from time to time, and at its own expense, to register and maintain any protection for the Foreground Intellectual Property, including filing and

prosecuting patent applications. Catapult shall ensure that its employees involved in the creation of the Foreground Intellectual Property give COLLABORATOR such assistance as COLLABORATOR may reasonably request in connection with the registration and protection of the Foreground Intellectual Property, including filing and prosecuting patent applications, and taking any action in respect of any alleged or actual infringement of the Foreground Intellectual Property (and for clarity, any out of pocket costs of Catapult associated with such assistance will be reimbursed by COLLABORATOR).

- 12.2 All Foreground Intellectual Property that constitutes an improvement to the Catapult Background Intellectual Property shall be owned by Catapult (“**Catapult Foreground Intellectual Property**”). Catapult grants to COLLABORATOR a non-exclusive, fully paid-up, royalty-free, worldwide, sublicensable licence under the Catapult Foreground Intellectual Property to undertake the Project. From the Termination Date, such license will extend to permit COLLABORATOR to replicate the Module, and to such extent as required to enable COLLABORATOR to otherwise replicate, utilise and develop the COLLABORATOR Process, and/or to produce and exploit the COLLABORATOR Product, provided that it is acknowledged that any licence to any Catapult Background Intellectual Property forming part of, or that is required to use such licensed Catapult Foreground Intellectual Property will remain subject to the restrictions and conditions of use in **Clause 11.3** regarding Third Party Intellectual Property.
- 12.3 To the extent that any Catapult Foreground Intellectual Property is capable of prospective assignment, COLLABORATOR now hereby assigns the Catapult Foreground Intellectual Property to Catapult; and to the extent any Catapult Foreground Intellectual Property cannot prospectively be assigned, COLLABORATOR shall assign such Catapult Foreground IP to Catapult as and when they are created, at the request of Catapult (and for clarity, any out of pocket costs of COLLABORATOR associated with such assignment will be reimbursed by Catapult).
- 12.4 To the extent that any COLLABORATOR Foreground Intellectual Property is capable of prospective assignment, Catapult now hereby assigns COLLABORATOR Foreground Intellectual Property to COLLABORATOR; and to the extent any COLLABORATOR Foreground Intellectual Property cannot prospectively be assigned, Catapult shall assign such COLLABORATOR Foreground Intellectual Property to COLLABORATOR as and when they are created, at the request of COLLABORATOR (and for clarity, any out of pocket costs of Catapult associated with such assignment will be reimbursed by COLLABORATOR).

13. CONFIDENTIAL INFORMATION

- 13.1 The Receiving Party undertakes:
- 13.1.1 to maintain as secret and confidential all Confidential Information of the Disclosing Party and its Affiliates;
- 13.1.2 where the Receiving Party is Catapult, to use such Confidential Information only for the purposes of making the Centre, Module and Inputs available to COLLABORATOR (and other Collaborators, solely with respect to their Confidential Information) in accordance with this Agreement and the QTA and for exercising its rights under this Agreement and the QTA, or where the Receiving Party is COLLABORATOR, for the purpose of exercising its rights, and complying with its obligations, under this Agreement and the QTA (in each case, a “**Permitted Purpose**”, and together, the “**Permitted Purposes**” as it applies to each Party); and
- 13.1.3 Subject to **Clause 13.3**, to disclose such Confidential Information only to those of its employees, officers, contractors, consultants, advisors, legal counsel, Affiliates and sublicensees pursuant to this Agreement (if any) to whom and to the extent that such disclosure is reasonably necessary for the Permitted Purposes. For clarity, notwithstanding the foregoing, Catapult shall not disclose COLLABORATOR’s or its Affiliates’ Confidential Information (or the Confidential Information of any other entity with which COLLABORATOR or any of its Affiliates is in business negotiations or has contracted or to which it owes a duty of confidence) to any other Collaborator, without (i) COLLABORATOR’s express prior written permission, on a case by case basis, and (ii) Catapult complying with **Clause 13.7** and ensuring that such collaborator is made aware of the confidential nature of the Confidential Information.
- 13.2 The provisions of **Clause 13.1** shall not apply to Confidential information which the Receiving Party can demonstrate by reasonable, written evidence:
- 13.2.1 was, prior to its receipt by the Receiving Party from the Disclosing Party or Alternative Disclosing Party, in the possession of the Receiving Party and at its free disposal;

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- 13.2.2 is subsequently disclosed to the Receiving Party without any obligations of confidence by a Third Party who has not derived it directly or indirectly from the Disclosing Party or Alternative Disclosing Party;
- 13.2.3 is or becomes generally available to the public through no act or default of the Receiving Party or its agents, officers, employees, Affiliates, advisors, contractors, consultants, legal counsel or sub-licensees;
- 13.2.4 is independently developed by the Receiving Party by individuals who have not had any direct or indirect access to the Disclosing Party's or Alternative Disclosing Party's Confidential Information; or
- 13.2.5 the Receiving Party is required to disclose (and so discloses) to the courts of any competent jurisdiction, or to any government regulatory agency or financial authority, provided that the Receiving Party shall (i) inform the Disclosing Party or Alternative Disclosing Party as soon as is reasonably practicable, and (ii) at the Disclosing Party's or Alternative Disclosing Party's request seek to persuade the court, agency or authority to have the information treated in a confidential manner, where this is possible under the court, agency, or authority's procedures, in which case, if the Confidential Information is treated in a confidential manner by the applicable court, agency or authority, such that it retains its confidential nature, **Clause 13.1** shall continue to apply to such Confidential Information.
- 13.3 The Receiving Party shall procure that all of its employees, officers, contractors, consultants, advisors, legal counsel, Affiliates and sub licensees pursuant to this Agreement (if any) who have access to any of the Disclosing Party's or Alternative Disclosing Party's information to which **Clause 13.1** applies, shall be made aware of and subject to these obligations and shall be subject to undertakings of confidentiality at least as restrictive as **Clause 13.1** and which apply to the Disclosing Party's or Alternative Disclosing Party's Confidential Information before being given access to the Disclosing Party's or Alternative Disclosing Party's Confidential Information, and the Receiving Party shall be liable to the Disclosing Party or Alternative Disclosing Party for any breach of its employees, officers, contractors, consultants, advisors, legal counsel, Affiliates or sub licensees of the terms of this **Clause 13**.
- 13.4 Upon any termination or expiry of this Agreement, the Receiving Party shall return to the Disclosing Party or Alternative Disclosing Party any documents or other materials that contain the Disclosing Party's or Alternative Disclosing Party's Confidential Information, including all copies made, and make no further use or disclosure thereof save that the Receiving Party shall not be obliged to purge or delete Confidential Information of the Disclosing Party or Alternative Disclosing Party from its IT systems that is stored by any automated back-up system, and shall be permitted to retain one (1) copy of all such Confidential information in its legal files solely for purposes of ensuring compliance with the terms of this Agreement, and shall not otherwise use or disclose such Confidential Information.
- 13.5 For the avoidance of doubt, and in light of Catapult's objective to disseminate best practices and foster the development of the regenerative medicine sector in the UK, Catapult shall be entitled to publish or otherwise disclose any of its Confidential Information (but excluding the terms of this Agreement), including the Catapult Background Intellectual Property and Catapult Foreground Intellectual Property.
- 13.6 Catapult (a) will procure that each other Collaborator, and any other Third Party contractor or other business partner working under contract with Catapult or any other Collaborator that has access to the Centre, agrees written obligations of confidence equivalent to those set out in this Agreement with Catapult in relation to COLLABORATOR'S Confidential Information (and COLLABORATOR'S Affiliates' Confidential Information (and the Confidential Information of any other entity with which COLLABORATOR or any of its Affiliates is in business negotiations or has contracted or to which it owes a duty of confidence)) and (b) will procure that (wherever possible with respect to such Third Parties other than Collaborators, but in all cases for Collaborators) COLLABORATOR will be given a third party right to enforce such confidentiality provisions.
- 13.7 For the purposes of this Agreement, Confidential Information shall also include any confidential information disclosed between COLLABORATOR and Catapult under (a) the confidentiality agreement between the Parties dated 27th May 2016, and (b) the heads of terms relating to the Collaboration between the Parties dated 10th November 2017. In relation to confidential information disclosed under these prior agreements, the terms of this Agreement shall supercede the terms in those prior agreements.

14. WARRANTIES

14.1 All Party Warranties

Each Party warrants, represents and undertakes to the other that:

- 14.1.1 it has full capacity and authority to enter into and to perform this Agreement;
- 14.1.2 there are no:
 - (a) actions, suits or proceedings pending or, to its knowledge, threatened against or affecting it before any court or administrative body or arbitration tribunal; or
 - (b) investigations by any Regulatory Authority pending or, to its knowledge, threatened against or affecting it;
- 14.1.3 once duly executed, this Agreement will constitute its legal, valid and binding obligations; and
- 14.1.4 it is not aware of any matters which might adversely affect its ability to perform its obligations pursuant to this Agreement.

14.2 Catapult Warranties

Catapult warrants, represents and undertakes to COLLABORATOR that from the Effective Date until the Termination Date:

- 14.2.1 it will use reasonable commercial endeavours to ensure it will always have the ability and all rights, titles and Necessary Consents to perform its obligations under this Agreement;
- 14.2.2 it will comply with its obligations under the QTA;
- 14.2.3 it will ensure that all other Collaborators are contractually obliged to comply with the operating requirements of the Centre so as to comply with GMP (as defined in the QTA) and Applicable Law, and will exercise appropriate diligence to ensure that all other Collaborators comply with these obligations;
- 14.2.4 it will maintain the Lease and perform all its obligations thereunder;
- 14.2.5 it will provide the inputs with all due care and skill and in any event in accordance with Applicable Law; and
- 14.2.6 it will make available the Centre and the Module in accordance with the provisions of this Agreement and in any event in accordance with all Applicable Law.

14.3 COLLABORATOR Warranties

COLLABORATOR warrants, represents and undertakes to Catapult that from the Effective Date until the Termination Date it will:

- 14.3.1 use reasonable commercial endeavours to ensure it will at all times have the ability and all rights, titles and Necessary Consents to perform its obligations under this Agreement;
- 14.3.2 perform both its obligations under this Agreement and all activities in respect of the Project in accordance with all Applicable Law and the Code of Conduct; and
- 14.3.3 perform COLLABORATOR Responsibilities.

14.4 Intellectual Property Warranties

14.4.1 Each Party represents, warrants, and undertakes to the other Party that:

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

- (a) it has all right, title, and interest in and to its Background Intellectual Property or has, in the case of licensed Background Intellectual Property, the right to use such licensed Background Intellectual Property for the Project (subject to the Third Party Intellectual Property Rights in the categories of Catapult Background in **Clause 11.3**); and
- (b) it has not done, and will not do nor agree to do during the continuation of this Agreement, anything that would be inconsistent with the exercise by the other Party of the rights granted to it under this Agreement.

14.4.2 Without limiting the scope of **Clause 14.4.1** and except as expressly provided in **Clause 11.3**, neither Party makes any representation nor gives any warranty or undertaking:

- (a) as to the efficacy or usefulness of its Background Intellectual Property;
- (b) that the use of any of its Background Intellectual Property or the exercise of any of the rights granted under this Agreement will not infringe any other Intellectual Property or other rights of any other person;
- (c) that the use of any of its Background Intellectual Property under or in connection with this Agreement will produce Products of satisfactory or merchantable quality or fit for their intended purpose or that any Product will not have any latent or other defects, whether or not discoverable; or
- (d) as imposing any obligation on it to bring or prosecute actions or proceedings against third parties for infringement.

15. INDEMNITY

15.1 COLLABORATOR agrees to indemnify, and hold Catapult harmless from and against Liabilities that Catapult suffers or incurs arising out of or in connection with:

- 15.1.1 any claim or proceedings made, brought or threatened against Catapult by a Third Party in respect of the COLLABORATOR Product or Process, or when in respect of the Project, whenever a Third-Party claim or proceeding is made, brought or threatened against Catapult because of the negligence, omission or wilful misconduct of COLLABORATOR, its employees, agents, contractors, visitors or subcontractors;
- 15.1.2 any loss of or damage to the tangible property or equipment belonging to a Third Party caused by or resulting from the negligence, omission or wilful misconduct of COLLABORATOR, its visitors, employees, agents, contractors, or subcontractors; and/or
- 15.1.3 any costs relating to an investigation, action or proceeding by a Regulatory Authority which arises because of COLLABORATOR's material breach of this Agreement.

15.2 Catapult agrees to indemnify, and hold COLLABORATOR harmless from and against Liabilities that COLLABORATOR suffers or incurs arising out of or in connection with:

- 15.2.1 any claim or proceedings made, brought or threatened against COLLABORATOR by a Third Party whenever a Third-Party claim or proceeding is made, brought or threatened against COLLABORATOR because of the negligence, omission or wilful misconduct of Catapult, its employees, agents, visitors, contractors, or subcontractors;
- 15.2.2 any loss of or damage to the tangible property or equipment belonging to a Third Party caused by or resulting from the negligence, omission or wilful misconduct of Catapult, its visitors, employees, agents, contractors or subcontractors; and/or
- 15.2.3 any costs relating to an investigation, action or proceeding by a Regulatory Authority which arises because of Catapult's material breach of this Agreement.

15.3 Indemnification of either party under this **Clause 15** is conditional upon: (a) the extent that the indemnified claim is caused by or resulting from the negligence, omission or wilful misconduct of the indemnified party, its employees, agents or subcontractors, or their failure to take any measures as are reasonable in the relevant circumstances to mitigate the loss or damage that has occurred or may occur (in which case any portion of the claim not caused by or resulting from the negligence, omission or wilful

misconduct of the indemnified party, its employees, agents or subcontractors or failure to mitigate will remain valid for indemnification); (b) the indemnified party promptly, on becoming aware of such claim, notifying the indemnifying party of the existence of the relevant claim; (c) the indemnified party refraining from making any admissions in respect of the relevant claim; and (d) the indemnifying party having sole control over the defence and/or settlement of the relevant claim.

16. LIMITATION OF LIABILITY

- 16.1 Collaborators occupying the Centre generally, and COLLABORATOR and Catapult in particular with respect to this Agreement, in choosing to employ the Centre as a base for GMP manufacturing activities accept and acknowledge a degree of risk inherent in any multi-mode, shared occupancy manufacturing facility and the nature of the biological processes undertaken within. Occasional unforeseen situations may arise associated with, for example utilities, equipment and associated processes that have the potential to disrupt or have a detrimental impact on processing, including on the products manufactured and developed at the Centre, and/or the manufacturing process(es) utilised at the Centre, by Collaborators and COLLABORATOR.
- 16.1.1 In light of this, Catapult will procure from each Collaborator, prior to their occupation of the Centre, contractual agreement not to commence or sustain legal proceedings against COLLABORATOR (or any other Collaborators or Catapult) for damages, or any other financial reimbursement (“**Agreement Not to Sue**”), as a consequence of any unexpected and unintended consequences as a result of such a situation at the Centre as described in this **Clause 16.1 (“Unforeseen Risks”)** unless it is a result of attributable gross negligence or wilful misconduct of COLLABORATOR (or any other Collaborators or Catapult, as applicable), breach of confidence, material breach of any obligation under the relevant Collaborator’s (or, COLLABORATOR’S, or Catapult’s) collaboration agreement or quality agreement for the Centre, or material breach of Catapult SOPs or breach of Applicable Laws, by COLLABORATOR (or any other Collaborators or Catapult, as applicable) and shall procure a direct right of enforcement of such Agreement Not to Sue by COLLABORATOR against each such Collaborator or Catapult pursuant to the Contracts (Rights of Third Parties) Act 1999.
- 16.1.2 With respect to each Collaborator that Catapult has obtained an enforceable Agreement Not to Sue in accordance with **Clause 16.1.1**, which COLLABORATOR has a direct right to enforce against such Collaborator pursuant to the Contracts (Rights of Third Parties) Act 1999, COLLABORATOR agrees that it shall not commence or sustain legal proceedings against such a Collaborator for damages, or any other financial reimbursement, as a consequence of any Unforeseen Risks unless it is a result of attributable gross negligence or wilful misconduct of, or a breach of confidence, material breach of any obligation under the relevant Collaborator’s collaboration agreement or quality agreement for the Centre, or material breach of Catapult SOPs or breach of Applicable Laws by, such a Collaborator.
- 16.1.3 Catapult and COLLABORATOR, each agree not to commence or sustain legal proceedings against the other Party for damages, or any other financial reimbursement, as a consequence of any Unforeseen Risks unless it is a result of attributable gross negligence or wilful misconduct of the other Party, or is a breach of confidence, material breach of any obligation under this Agreement or the QTA, or a material breach of Catapult SOPs or breach of Applicable Laws, by the other Party.
- 16.1.4 This **Clause 16.1** is not intended to qualify, and is subject to and without prejudice to, each Party’s rights and obligations under **Clause 15 (Indemnity)**.
- 16.2 Catapult, COLLABORATOR, and all Collaborators are obliged to abide by the operating requirements of the Centre so as to comply with GMP (as defined in the Quality Technical Agreement) and exercise an appropriate duty of care such as to minimise the frequency and severity of events alluded to in **Clause 16.1**, thus offering each other mutual protection. In order to ensure that Catapult, COLLABORATOR and all Collaborators do not expose themselves to unreasonable financial risk as a result of such a situation, Catapult and COLLABORATOR (and Catapult will procure this of each other Collaborator) will ensure the continued and uninterrupted maintenance of an appropriate level of public liability, business continuity and professional indemnity insurances.
- 16.3 Without prejudice to **Clauses 16.1, 16.5, 16.6 and 16.7**, the maximum aggregate Liability of COLLABORATOR which arises from any single event which occur in any Year will be limited to [**] for any single event, with no limit on the number of events.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 16.4 Without prejudice to **Clauses 16.1, 16.5, 16.6 and 16.7**, the maximum aggregate Liability of Catapult which arises from events which occur in any Year will be limited to [**] for any single event, with no limit on the number of events. In no circumstance will any Party have any Liability for:
- 16.4.1 any indirect, special or consequential loss; or
- 16.4.2 any loss of profits, revenue, business opportunity, data, or goodwill (in each case whether such loss is direct or indirect).
- 16.6 Nothing in this Agreement limits or excludes any person's liability to the extent that it may not be so limited or excluded by law, including any such liability for death or personal injury caused by that person's negligence, or liability for fraud or fraudulent misrepresentation.
- 16.6 Without prejudice to **Clause 16.5**, nothing in this Agreement will operate to exclude or restrict COLLABORATOR's Liability:
- 16.6.1 under the indemnity contained in **Clause 15.1**; or (in each of **Clauses 16.6.2 and 16.6.3** below, other than when the specific conditions stipulated in the Agreement are met so as to justify otherwise);
- 16.6.2 to pay the Financial Contributions; or
- 16.6.3 to pay the Compensations.
- 16.7 The Parties agree that they have negotiated this **Clause 16** and the allocation of risk in this Clause is a fair and equitable position.

17. DURATION AND TERMINATION

- 17.1 This Agreement, and the licences granted hereunder, shall come into effect on the Effective Date and, unless terminated earlier in accordance with this **Clause 17** or unless specified in the continuing obligations provisions of this Agreement as having continued effect, shall continue in force for [**] from the Actual Occupation Date ("Initial Period") after which date the Term will terminate automatically by expiry.
- 17.2 COLLABORATOR will have an option to extend the Initial Period on a rolling basis for further periods of up to [**] on condition:
- 17.2.1 COLLABORATOR provides 12 months' advance notice of the end of the Initial Period (or any extension thereof) of its intention to extend the Term;
- 17.2.2 COLLABORATOR has consistently materially complied with its material obligations (but this does not preclude multiple, repeated breaches of minor obligations, which have been raised by Catapult with COLLABORATOR, constituting a material breach so as to prevent COLLABORATOR'S right to this option) in the Collaboration Agreement throughout the term of the Collaboration Agreement up to the date the option is exercised;
- 17.2.3 Catapult intends to continue the operation of the Centre beyond the Initial Period (or any extension thereof); and
- 17.2.4 the terms of any extensions are mutually agreed, with both Parties acting reasonably and in good faith to negotiate such terms, although it is agreed such terms will be substantially the same as those in this Agreement, save for any changes required because of changes in law or regulation, or required in order to enable compliance with GMP or to maintain the Centre's licence. The Financial Contributions to be made by COLLABORATOR for the period of the applicable extended term will be based on those prevailing on the date the option is exercised.
- 17.3 COLLABORATOR shall be able to terminate on the provision of [**] written notice to Catapult.
- 17.4 The Parties may terminate this Agreement at any time by agreement to do so in writing signed by the authorised signatories of the Parties and the provisions of **Clauses 18.1** shall not apply.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 17.5 For a period of 12 months from the date that Catapult announces that the second set of standard modules (“**Phase 2**”) is available for reservation, on condition COLLABORATOR is in continuing occupation of the Module and has been in continuing material compliance with its obligations and warranties under this Agreement at the time the option is exercised, Catapult grants to COLLABORATOR the non-transferrable option to:
- 17.5.1 negotiate (with both Parties acting reasonably and in good faith), for occupation of one additional module in Phase 2 on terms to be agreed in an amendment to this Agreement (but with the financial contributions relative to manufacturing area in any additional module in Phase 2 not to be materially different from the financial contributions prevailing that apply to modules available in Phase 2 on the date the option is exercised); and
- 17.5.2 negotiate (with both Parties acting reasonably and in good faith), to transfer the Module to a module in Phase 2 on terms of occupation, relative to manufacturing space area, to be unchanged from those of the Module (but with the financial contributions relative to manufacturing area not to be materially different from the financial contributions prevailing that apply to modules available in Phase 2 on the date the option is exercised), save that COLLABORATOR shall be responsible for any reasonable costs of relocation including Catapult inputs for Manufacturing Space de-contamination and qualification costs. Any such transfer to Phase 2 will take into consideration any reasonable location and timing requirements of COLLABORATOR.
- 17.6 If either option is exercised by COLLABORATOR, the Facility, Integral and Business Rates Contributions attributable to Phase 2 will be equally apportioned between all Collaborators occupying Phase 2 modules. For the avoidance of doubt, COLLABORATOR will be responsible for no more than a [**] share of all Facility, Integral and Business Rates Contributions attributable to Phase 2.
- 17.7 If either option is not exercised during the period set out above, then that option will lapse and Catapult will owe no further obligation to COLLABORATOR regarding Phase II modules.
- 17.8 Either Party may elect to terminate this Agreement at any time by notice in writing to the other Party, such notice to take effect as specified in the notice:
- 17.8.1 if the other Party is in material breach of this Agreement (including any breach of **Clause 20**) and, in the case of a breach capable of remedy within 90 days, the breach is not remedied within 90 days of the party receiving notice specifying the breach and requiring its remedy; or
- 17.8.2 if (A) the other Party becomes insolvent or unable to pay its debts as and when they become due; or (B) an order is made or a resolution is passed for the winding up of the other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction); or (C) a liquidator, administrator, administrative receiver, receiver, or trustee is appointed in respect of the whole or any part of the other party’s assets or business; or (D) the other Party makes any composition with its creditors; or (E) the other Party ceases to continue its business; or (F) as a result of debt and/or maladministration the other party takes or suffers any similar or analogous action in any jurisdiction
- 17.9 COLLABORATOR may elect to terminate this Agreement by notice in writing if, a party that is not an Affiliate obtains Control of Catapult.
- 17.10 A Party’s right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.
- 17.11 If there is destruction or damage to the Centre that leaves the whole or substantially the whole of the Centre unfit for occupation and use or inaccessible, and the Centre and Module have not been made fit for occupation and use and accessible within 5 months of such damage or destruction, and within that 5 month period it has been agreed that there is no possibility that the Centre and Module can be made fit for occupation and GMP operation within another 12 months from the end of that 5 month period, then either Party may terminate this Agreement immediately by written notice to the other. Such right of termination, If not exercised, shall continue until such time as the Centre and Module are made fit for occupation and use, and accessible, again.
- 17.12 If there is destruction or damage to the Centre by any of the Insured Risks that leaves the whole or substantially the whole of the Centre and / or the Module unfit for occupation and use or inaccessible,

then, save to the extent that the Catapult's insurance has not been vitiated or policy moneys refused because of any act or default of COLLABORATOR then the Facility Contribution, the Activity Related Inputs Contributions, the Integral Contributions, and the Business Rates or a fair proportion of them shall not be payable from and including the date of such damage or destruction until the earlier of the date that the Module is once again fit for occupation end use and accessible end the date 2 years from and including the date of such damage or destruction.

18. CONSEQUENCES OF TERMINATION

- 18.1 COLLABORATOR recognises that considerable planning and advanced preparation is required to ensure timely COLLABORATOR occupation of the Module. In recognition of the opportunity cost of reserving a Module for COLLABORATOR, If COLLABORATOR serves notice to terminate this Agreement in any circumstances other than as set out in **Clauses 17.3 or 17.4**, COLLABORATOR will compensate Catapult as follows: Following notice to terminate, COLLABORATOR will pay to Catapult the sum equivalent [**].
- 18.2 The provisions of **Clause 18.1** shall not apply where this Agreement is terminated in accordance with **Clause 20**. The Compensations will be payable by COLLABORATOR in the event Catapult terminates under **Clause 17.8.1** because of a material breach committed by COLLABORATOR that is either not remediable, or that is not remedied within 90 days or less where a remedy is possible.
- 18.3 Upon termination of this Agreement for any reason (and unless otherwise agreed by the Parties in a subsequent, written agreement, including any agreement entered into in accordance with the provisions of **Clause 9(c)**):
- 18.3.1 the provisions of **Clauses 1, 11,3, 11.4, 12.1 to 12.4** inclusive, **13, 14, 15, 16, 18, 19, 21, 22, 23, 24, 28, 31, 32, 33** and **36** shall remain in force; and
- 18.3.2 the Collaboration will terminate, subject to any subsisting and continuing obligations.

19. INSURANCE

- 19.1 Catapult shall take out with a reputable insurance company and maintain at all times during the Term of this Agreement buildings, employers liability, professional indemnity, public and product liability insurance including against all loss of and damage to the Module, the Centre, and Injury to persons including death arising out of or in connection with this Agreement. Such insurances may be limited in respect of one claim provided that such limit must be at least [**]. Product liability insurance shall continue to be maintained for a further [**] from the end of the term of this Agreement.
- 19.2 COLLABORATOR shall take out with a reputable insurance company, and maintain at all times during the Term of this Agreement professional indemnity, public and product liability insurance including against all loss of and damage to the Module and Centre, injury to persons including death arising out of or in connection with this Agreement, and against all loss of and damage to any COLLABORATOR owned equipment, or COLLABORATOR personnel personal effects within the Module or in the Centre generally. Copies of COLLABORATOR insurance certificates will be provided for Catapult's records annually on request. Such insurances may be limited in respect of one claim provided that such limit must be at least [**]. Product liability insurance shall continue to be maintained for a further [**] from the end of the Term. COLLABORATOR acknowledges that Catapult will have no responsibility for any COLLABORATOR owned equipment or any COLLABORATOR personnel personal effects located in the Module or any other part of the Centre save where any damage to such is caused directly by Catapult negligence or intentional misconduct.

20. ANTI-BRIBERY AND ANTI-CORRUPTION

- 20.1 Each Party agrees that, in connection with this Agreement and the Project, they shall each, (and shall procure that their respective officers, employees, agents and any other persons who perform services for them or on their behalf in connection with this Agreement shall):
- 20.1.1 not commit any act or omission which causes or could cause the other Party to breach, or commit an offence under, any laws relating to anti-bribery and/or anti-corruption including Foreign Corrupt Practices Act in the United States and the UK Anti-Bribery Act;
 - 20.1.2 keep accurate and up to date records showing all payments made and received and all other advantages given and received in connection with this Agreement and the steps taken to comply with this **Clause 20**, and permit the other Party to inspect those records as reasonably required;
 - 20.1.3 promptly notify the other Party of:
 - 20.1.3.1 any request or demand for any financial or other advantage received by it (or that person); and
 - 20.1.3.2 any financial or other advantage it (or that person) give or intend to give whether directly or indirectly in connection with this Agreement; and
 - 20.1.4 promptly notify the other Party of any breach of this **Clause 20**.
 - 20.1.5 in the case of Catapult, ensure that all other collaborators are contractually obliged to comply with equivalent obligations as set out above.
- 20.2 Any breach of this **Clause 20** shall constitute a material breach.

21. PUBLICITY

The Parties agree consent is required in before use of the other's name, or any adaptation of their name, or any of their logo(s), trademark(s), or other of their device(s) in any advertising, promotional, or sales materials (however, they also agree that such consent is not to be unreasonably withheld).

22. STATE AID

- 22.1 The parties acknowledge that Catapult is a 'Research Organisation' as defined under European Union legislation and has an obligation to ensure, and is subject to audits to demonstrate, that all activities it undertakes are compliant with EU state aid rules, including its activities under this Agreement. The parties therefore agree that, notwithstanding any other provision of this Agreement:
- 22.1.1 Catapult shall be entitled to cooperate fully with any investigation by any grant funder of Catapult or by the European Commission or any court of law with respect to this Agreement regarding the grant/alleged grant of state aid and the provision of inputs hereunder and COLLABORATOR shall, if so requested by Catapult, promptly provide to Catapult all reasonable and necessary assistance in connection with any such investigation(s);
 - 22.1.2 Catapult shall keep COLLABORATOR informed of any active and specific investigation into this Agreement and, where possible, liaise with COLLABORATOR concerning any response to the European Commission; and
 - 22.1.3 the parties shall comply with any ruling of the European Commission or court of law in relation to the application of the EU state aid rules to this Agreement.
- 22.2 The obligations set out in **Clause 22.1** above shall subsist for a period of 10 years from the date of this Agreement, notwithstanding any earlier termination of this Agreement.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

23. NOTICES

23.1 Any notice required to be given under this Agreement shall be given in writing and sent by prepaid airmail post or courier, delivered personal, or sent by email to the following addresses or such other address as may be notified by the relevant party from time to time in writing:

To Catapult

If sent by post to:

Cell Therapy Catapult
12th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London
SE1 9RT
United Kingdom

For the attention of:

[**]

If sent by email, to:

[****]

**To
COLLABORATOR:**

If sent by post to:

Stevenage Bioscience
Catalyst
Gunnels Wood Road
Stevenage
Herts SG1 2FX

For the attention of:

[**] Chief
Development
Officer

If sent by email, to:

[****]

23.2 Any notice so sent shall be deemed to have been duly given:

23.2.1 if sent by personal delivery or courier, on delivery at the address of the relevant party;

23.2.2 if sent by prepaid airmail post, five days after the date of posting; and

23.2.3 if sent by email, only on acknowledgement of receipt, such acknowledgement not being an automated message.

24. FURTHER ASSURANCES

Each Party shall, as and when requested by the other Party and without charge, do all such acts and execute all such documents as may be reasonably necessary to give full effect to the provisions of this Agreement.

26. ENTIRE AGREEMENT

25.1 This Agreement constitutes the entire agreement between the Parties and supersedes and replaces any and all previous agreements, understandings or arrangements between the parties, whether oral or in writing, relating to its subject matter.

25.2 The Parties acknowledge that in entering into this Agreement they do not rely on any statement, representation (including, without limitation, any negligent misrepresentation but excluding any fraudulent misrepresentation), warranty, course of dealing, custom, understanding or promise except for those expressly set out in this Agreement.

25.3 The Parties irrevocably and unconditionally waive any rights and/or remedies they may have to the fullest extent permitted by law (including without limitation the right to claim damages and/or to rescind this Agreement) in respect of any misrepresentation (including, without limitation, any negligent misrepresentation but excluding any fraudulent misrepresentation).

25.4 Except as expressly set forth in this Agreement, neither Party grants to the other by implication, estoppel or otherwise, any right, title, licence or interest in any Intellectual Property right.

26. VARIATION

- 26.1 Subject to **Clause 26.2**, no variation or amendment to this Agreement shall be effective unless it is made in writing and signed by the duly authorised representatives of both Parties.
- 26.2 The following principles will be adhered to in the event a change is proposed by Catapult to **Schedule 8** (Warehouse and Procurement Management Provisions), **Schedule 9** (Quality Control), **Schedule 10** (IT Infrastructure), and **Schedule 12** (Module and Centre Specifications) only:
- 26.2.1 If the proposed change has no material impact on COLLABORATOR Product(s) or Process(es), or COLLABORATOR'S compliance with GMP guidelines or would not require COLLABORATOR to amend or change any regulatory filing or regulated procedure, Catapult may enact the change by a written notification (signed by a member of Catapult's Quality team) to COLLABORATOR, such written notification forming an amendment to this Agreement. Catapult will provide at least 30 days notification to enable COLLABORATOR to assess impact ahead of any impact occurring;
- 26.2.2 If the proposed change has a material impact on the COLLABORATOR Product(s) or Process(es), or COLLABORATOR'S compliance with GMP guidelines, or would require COLLABORATOR to amend or change any regulatory filing or regulated procedure, such change will require the mutual written consent of the Parties in the form of an amendment including the authorised signatories of their respective quality assurance teams where relevant to quality procedures to this Agreement in accordance with **Clause 26.1**;
- 26.2.3 If COLLABORATOR does not agree that a change proposed by Catapult to fall under **Clause 26.2.1** has no material impact, the matter will be referred to the Steering Committee for resolution, and if no agreement is reached within a reasonable period, then resolved through the use of the Expert Determination Procedure under **Schedule 13**.
- 26.2.4 This section shall not override the Quality Technical Agreement in relation to changes relating to quality.

27. ASSIGNMENT AND SUB-CONTRACTING

- 27.1 Except as provided in **Clause 27.2**, neither Party shall assign, sub-contract, mortgage, charge, or otherwise transfer any rights or obligations under this Agreement, without the prior written consent of the other Party.
- 27.2 Catapult will be entitled to sub-contract any of its obligations under this Agreement, provided that it shall ensure any relevant obligations are passed on to such sub-contractor and Catapult shall be responsible for the performance of such sub-contractor.

28. WAIVER

No failure or delay by a party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

29. SEVERABILITY

If any provision (or part of any provision) of this Agreement is held to be invalid, void or otherwise unenforceable by a court of competent jurisdiction from whose decision no appeal is available, or from whose decision no appeal is made within the applicable time limit, then the provision (or relevant part of the provision) shall be re-written to be compliant where possible or omitted and the remaining provisions of this Agreement (and parts of the relevant provision, as applicable) shall continue in full force and effect. Should a material provision be rendered void, unenforceable or invalid by a court, either Party may terminate this Agreement within 30 days of the relevant court finding of voidness, unenforceability or invalidity.

30. RELATIONSHIP OF THE PARTIES

Nothing in this Agreement is intended to, or shall be deemed to, establish or imply any agency, partnership or joint venture between the Parties. Neither Party shall act or describe itself as the agent of the other Party and neither Party shall have, or hold itself out as having any authority to make commitments for or on behalf of the other Party.

31. THIRD PARTY RIGHTS

This Agreement does not create any right enforceable by any person who is not a Party to it save for (i) with respect to **Clause 13.6** which the Parties agree may be directly enforceable by any other Collaborator that has occupied the Centre concurrently with the COLLABORATOR, provided that COLLABORATOR is able to directly enforce provisions equivalent to **Clause 13** with respect to COLLABORATOR's Confidential Information in a collaboration agreement between such Collaborator and Catapult, and (ii) as provided in **Clause 16.1**.

32. GOVERNING LAW AND JURISDICTION

This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of England and Wales.

The Parties to this Agreement irrevocably agree that the courts of England shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims), except that a Party may seek an interim injunction in any court of competent jurisdiction.

33. DISPUTE RESOLUTION PROCEDURE

33.1 If a dispute arises out of or in connection with this Agreement or the performance, validity or enforceability of it (a "**Dispute**"), then, except as expressly provided in **Clauses 7.2** and **26.2.3**, the Parties shall follow the procedure set out in this clause:

- (a) either Party shall give to the other written notice of the Dispute, setting out its nature and full particulars ("**Dispute Notice**"), together with relevant supporting documents. On service of the Dispute Notice, the Steering Committee shall attempt in good faith to resolve the Dispute within 20 days, and if they're unable to do so, then the Dispute shall be referred to the Chief Business Officer of Catapult, and Chief Operating Officer of COLLABORATOR, who shall attempt in good faith to resolve the Dispute;
- (b) if the Chief Business Officer of Catapult and Chief Operating Officer of COLLABORATOR are for any reason unable to resolve the Dispute within 30 days of the matter being referred to them from the Steering Committee under paragraph (a) above, then unless the Parties mutually agree to enter into mediation in good faith to settle the Dispute in accordance with the CEDR Model Mediation Procedure (but with no obligation on either Party to do so), then either Party shall be free to commence legal proceedings and the Dispute shall be finally resolved by the courts of England and Wales in accordance with **Clause 32** (Governing Law and Jurisdiction).

34. COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute a duplicate original of this agreement, but all the counterparts shall together constitute the same agreement. If this Agreement is executed in counterparts, it shall not be effective unless and until each Party has executed and delivered a counterpart to the other Party.

35. FORCE MAJEURE

Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement that result from circumstances beyond the reasonable control of that Party (each Party having in place appropriate disaster recovery and fail-safe measures to minimise the risk of force majeure), including without limitation labour disputes involving that Party. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so. To the extent any force majeure continues for more than 3 continuous months, the affected Party may serve 14 days written notice to terminate this Agreement. Such termination shall be automatic on expiry of the 14 day period provided the force majeure event has not ceased.

36. DATA PROTECTION

36.1 In this Agreement the terms "**Personal Data**", "**Data Processor**", "**Data Subject**", "**Process**" and "**Data Controller**" are as defined in the Data Protection Act 1988 ("**Act**") or the GDPR or other data protection legislation in force in the UK from time to time. Each Party shall comply with its respective obligations under the provisions of the Act.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

- 36.2 COLLABORATOR shall act as the Data Controller in respect of any Personal Data Processed by Catapult relating to this Agreement, the Project and/or Services and in compliance with COLLABORATOR's obligations as such under the Act.
- 36.3 Insofar as COLLABORATOR provides or otherwise makes available Personal Data to Catapult and such Personal Data is Processed by Catapult, or if Catapult is required to Process Personal Data in connection with this Agreement; Catapult shall (a) keep such Personal Data strictly confidential; (b) only distribute to employees of Catapult to the extent such employees require access to such Personal Data for the performance of the Agreement; (c) not transfer such Personal Data to any third party (including any sub-contractor) without the prior written approval of COLLABORATOR; (d) only Process the Personal Data for purposes authorised by COLLABORATOR and in accordance with any instructions provided by COLLABORATOR (and for clarity, any purpose set out in this Agreement will be deemed to meet this requirement to the extent processing is required for the performance of that purpose); and (g) keep such Personal Data secure in accordance with the requirements of the Act and the principles articulated in the Act. Should Catapult receive any request from a Data Subject in relation to any Personal Data provided by COLLABORATOR, Catapult shall immediately pass on such Data Subject request to COLLABORATOR.
- 36.4 To the extent required under data protection legislation, each Party will permit and assist the other to carry out any privacy impact assessments or other data protection assessments reasonably required under data protection legislation.

AGREED by the parties through their duly authorised representatives on the date written at the start of this Agreement:

For and on behalf of:
Freeline Therapeutics Limited

Signed: [**]
Full Name: [**]
Job Title: CEO

For and on behalf of
Cell Therapy Catapult Limited

Signed: [**]
Full Name: [**]
Job Title: CEO

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SCHEDULE 1

THE PROJECT

[**]

SCHEDULE 2

Part 1 Occupation of Module

1. Definitions

In this Schedule 2:

- 1.1 “**Co-location Fee**” means the aggregate of the Facility Contribution and proportion of business rates payable under **Clauses 8.4.1** and **8.4.2** of this Agreement.
- 1.2 “**end of the Licence Period**” means the expiry of the Term or its earlier termination pursuant to **Clause 17** of this Agreement.

2. Occupation of the Module

- 2.1 Catapult permits COLLABORATOR to occupy the Non-Manufacturing Office from the Effective Date until the Actual Occupation Date for general administration and project management purposes connected with the Project.
- 2.2 Catapult permits COLLABORATOR to occupy the Module for the Permitted Use from the Actual Occupation Date until the end of the Licence Period together with the rights mentioned in **Part 2** of this **Schedule 2** and subject to the rights reserved to Catapult in **Part 3** of this **Schedule 2** and subject further to payment of the Co-location Fee in accordance with **Clause 8** of this Agreement.
- 2.3 Subject to reasonable notice to Catapult, COLLABORATOR’s subcontractors may enter and use the Module and Common Access Areas (as necessary only to gain access to the Module) under COLLABORATOR’s supervision, for the purposes of the Project, provided that COLLABORATOR shall ensure that any relevant obligations are passed on to such subcontractors and COLLABORATOR shall be responsible for the actions of such subcontractors while at the Centre.
- 2.4 Catapult permits COLLABORATOR to access the Module at any time (24 hours a day, 7 days a week, 365 days per year), except in situations of Centre shutdown / an emergency.

3. COLLABORATOR’s Covenants and Acknowledgement

- 3.1 COLLABORATOR covenants with Catapult as follows:
 - 3.1.1 to keep the Module clean, tidy and clear of rubbish;
 - 3.1.2 not to use the Module other than for the Permitted Use;
 - 3.1.3 not to make any alteration or addition to the Module or the Centre without the prior written consent of Catapult (such consent not to be unreasonably withheld, delayed or conditioned);
 - 3.1.4 not to display any advertisement, signboards, nameplate, inscription, flag, banner, placard, poster, signs or notices at the Module or elsewhere in the Centre (that is not on agreed signage areas) without the prior written consent of Catapult, such consent not to be unreasonably withheld, delayed or conditioned;
 - 3.1.5 not to do or permit to be done in the Module anything which is illegal or which may be or become a disruption, nuisance (whether actionable or not), annoyance, inconvenience, or disturbance to Catapult, or to other occupiers of the Centre or to the owner or occupier of neighbouring property;
 - 3.1.6 not to cause or permit to be caused any damage (other than general wear and tear as would be expected from general usage of the Module over time for the Permitted Use) to:
 - 3.1.6.1 the Module, Centre or any neighbouring property; or
 - 3.1.6.2 any property of the owners or occupiers of any neighbouring property;

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- 3.1.7 not to obstruct the Common Access Areas, make them dirty or untidy or leave any rubbish on them and to otherwise keep the Common Access Areas free and clear of any equipment, materials or personal property of COLLABORATOR;
 - 3.1.8 not to apply for any planning permission in respect of the Module unless agreed in advance in writing with Catapult;
 - 3.1.9 (In as much as this applies to COLLABORATOR as the end user of any such Supplies) to comply with all Applicable Laws and with any recommendations of the relevant suppliers relating to the supply and removal of electricity, gas, water, sewage, telecommunications and data and other services and utilities to or from the Module;
 - 3.1.10 to observe any reasonable rules and regulations Catapult makes and notifies to COLLABORATOR from time to time in writing governing COLLABORATOR's use of the Module and the Common Access Areas; and
 - 3.1.11 not to do anything on or in relation to the Module and the Centre that would or might cause Catapult to be In breach of Catapult's covenants and the conditions contained in the Lease; and
 - 3.1.12 to comply with Catapult's reasonable requests for cooperation with respect to any further development of the Centre and the Module and not to raise any objection to any noise and disturbance resulting from such further development on condition Catapult uses reasonable endeavours to minimise any disruption to the COLLABORATOR's activities within the Module and the Centre.
- 3.2 COLLABORATOR acknowledges that Catapult is entitled to exclusive control and possession of the Centre and the Module and nothing contained in this Agreement creates any relationship of landlord and tenant or any other relationship other than that of a licensor and licensee between Catapult and COLLABORATOR.

4. Relocation of Module

Catapult shall be entitled, upon provision of as much written notice as possible (target notice period will be 12 months, but it will not be less than 6 months) to COLLABORATOR, from time to time, to relocate COLLABORATOR to a different location within the Centre provided that:

- (a) Catapult has first considered all reasonable alternatives to relocation (taking into account the costs that may be incurred by COLLABORATOR due to any programme delays resulting from such relocation) while discussing such alternatives with COLLABORATOR;
- (b) there is made available to COLLABORATOR a Module which is in all material respects is the same as the Module; and (c) the Collaborator is permitted to continue occupation of the Module for 3 months in tandem with that of the proposed replacement module for the latter 3 months of the 6 month notice period to enable a smooth handover. The costs and expenses incurred in relocating COLLABORATOR shall be borne by Catapult, and, for the avoidance of doubt, (i) for such period as COLLABORATOR occupies two modules pursuant to this **paragraph 4**, COLLABORATOR shall, nonetheless, be charged Contributions only for occupation of one module, and (ii) the relocation shall not cause any increase in COLLABORATOR's Contributions as compared to those payable before the relocation.

5. Termination

- 5.1 At the end of the Licence Period:
- 5.1.1 COLLABORATOR's rights to occupy the Module will automatically terminate;
 - 5.1.2 COLLABORATOR will leave the Module in the same state and condition (taking into account normal "wear and tear" usage and excluding any damage caused by Catapult or any Third Party authorised to access the Module by Catapult or any Insured Risks), with all fixtures, fittings and equipment as were provided to it by Catapult as recorded in the Schedule of Condition and Inventory referred to in **Schedule 7**.
- 5.2 The termination of COLLABORATOR's rights to occupy the Module will be without prejudice to any subsisting breach of COLLABORATOR's obligations contained in this **Schedule 2**.

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Part 2 A – Rights granted to COLLABORATOR

The following rights are granted to COLLABORATOR in common with Catapult, any person authorised by Catapult and all other Collaborators but subject to Catapult's rights:

1. Running of services

To connect to and use the existing service media at the Centre for the passage of Supplies to and from and to the Module.

2. Access and servicing

- 2.1 Access to and from the Module on foot only over the Common Access Areas from time to time designated by Catapult for COLLABORATOR's use. For the avoidance of doubt, other Collaborators shall not have access to or use of the Module.
- 2.2 To use any service area from time to time designated by Catapult for COLLABORATOR's use for loading and unloading and otherwise servicing the Module and the service roads with or without vehicles to come and go to and from that service area.

3. Refuse disposal

To deposit rubbish in any receptacles or waste compactors within the Common Access Areas provided by Catapult for that purpose and designated by Catapult for the use of COLLABORATOR.

4. Support and shelter

Support and shelter for the Module from the Centre.

5. Parking

Use of up to 6 parking spaces designated by Catapult, from time to time, as available for COLLABORATOR'S use.

6. Signage

To exhibit COLLABORATOR's name in such form, shape and size as Catapult approves (acting reasonably) on any appropriate directory board within the Centre.

7. Toilet facilities

To use any toilet facilities Within the Common Access Areas designated by Catapult as facilities for the use of COLLABORATOR.

8. Escape

On foot only, in emergencies and for fire escape drills, to use all fire escape routes in the Centre designated by Catapult for the use of COLLABORATOR whether or not forming part of the Common Access Areas.

9. QC Lab Space

The Centre has Catapult-operated quality control laboratories and three additional QC laboratories of 15 to 16 square meters. From time to time COLLABORATOR may request access to, and use of one of these additional QC laboratory spaces. Catapult may, reserving its sole discretion, grant access to, and use of such QC laboratory space as may be available at the time of request under the terms of an Additional Input Agreement.

Part 2 B – Rights granted to COLLABORATOR II

The Parties acknowledge that certain licences to perform alterations to the Module contained within the On-boarding Project may be granted as Additional Inputs are agreed between the Parties in accordance with **Clause 9(c)** that may require further modifications to the Module to be carried out.

Part 3 - Rights reserved to Catapult

The following rights are excepted and reserved to Catapult and all those authorised by Catapult:

1. Support, shelter, light and air

- 1.1 Support and shelter for the remainder of the Centre from the Module.
- 1.2 All rights of light or air to the Module that now exist or that might (but for this reservation) be acquired over any other land.

2. Running of services

The passage and running of Supplies from and to the remainder of the Centre through existing Conducting Media (if any) within the Module.

3. Entry on to the Module

- 3.1 To enter the Module during regular business hours and with maximum possible notice to COLLABORATOR and on not less than 24 hours prior notice, but excluding any period in which such access would disrupt preparations for manufacturing or when COLLABORATOR Products are being manufactured In the Manufacturing Space for any purpose including to:
 - 3.1.1 perform any action required under the QTA or to maintain GMP compliance within the Centre— however with respect to this **Clause 3.1.1** only, no notice will be required (unless notice is required under the QTA, and providing the visits do not pose a material risk to the quality of Products being manufactured at the time or expose Catapult staff to safety risks));
 - 3.1.2 estimate the current value or rebuilding cost of the Centre for Insurance or any other purpose;
 - 3.1.3 install, Inspect, clean, maintain, replace and to take readings from metering equipment, heat cost allocators and thermostatic radiator valves within or relating to the Module and to prepare an energy performance certificate;
 - 3.1.4 do anything that Catapult is expressly entitled or required to do under this Agreement or the Lease or for any other reasonable purpose in connection with this Agreement Including to Inspect the state of repair and condition of the Module;
 - 3.1.5 carry out any works to the Module to improve their environmental performance;
 - 3.1.6 build on or into any boundary or party walls on or adjacent to the Module (but only to the extent this cannot be carried out without entry to the Module);
 - 3.1.7 inspect, clean, maintain, repair, alter, decorate, rebuild or carry out works upon the Centre (but only to the extent this cannot be carried out without entry to the Module);
 - 3.1.8 carry out any of the necessary Inputs (but only to the extent this cannot be carried out without entry to the Module); or
 - 3.1.9 for any other reasonable management purpose (but only to the extent that the required action is agreed with COLLABORATOR first and that this action cannot be carried out without entry to the Module).
- 3.2 Where reasonably possible, Catapult, or its contractors, will undertake any works described in this **paragraph 3** in a manner which causes the least disruption to the COLLABORATOR and its use of the Module as possible.
- 3.3 Subject to **Clause 3.1.1**, right of entry to the Module under this **paragraph 3** shall only be permitted to the extent that it does not disrupt the activities of COLLABORATOR within the Module. In the event that such entry would disrupt the activities of the COLLABORATOR within the Module, the Parties shall, acting reasonably, agree appropriate times and dates at which such entry and works may take place in order to minimise any such disruption.

4. Common Access Areas and Conducting Media

- 4.1 In an emergency, or when works are being carried out to them, to close off or restrict access to the Common Access Areas, so long as (except an emergency) alternative facilities are provided that are not materially less convenient.
- 4.2 To change, end the use of or reduce the extent of any Common Access Areas or Conducting Media so long as alternative facilities are provided that are not materially less convenient or, if no alternative is provided, the use and enjoyment of the Module is not adversely affected. In such event, Catapult shall provide all Collaborators and COLLABORATOR with a reasonable amount of advance notice as part of the Collaborator Forums at **Schedule 15**.

5. Adjoining Property

To carry out works of construction, demolition, alteration or redevelopment on Centre and any adjoining property (and to permit others to do so) as Catapult in its absolute discretion considers fit (whether or not these works interfere with the flow of light and air to the Module). Catapult shall use all reasonable efforts to ensure that any such works do not interfere with COLLABORATOR's use of the Module and undertaking of the Project. Catapult shall provide all Collaborators and COLLABORATOR with reasonably advanced notice of any such works through the Collaborator Forums.

6. Plant, equipment and scaffolding

The right, where necessary, to bring plant and equipment onto the Module and to place scaffolding and ladders upon the exterior of or outside any buildings on the Centre (Including the Module) on not less than 24 hours prior notice.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Part 4 Plans of the Module and the Centre

[**]

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SCHEDULE 3

Financial Contributions

	Contribution per module
Facility Contribution per year from the Actual Occupation Date	[**]
Business Rates per year from the Actual Occupation Date	[**]
Integral Inputs Contribution per year from the Actual Occupation Date* (estimated)	[**]
Activity Related Input Contribution* (estimated)	These contributions are dependent on Collaborator readiness, activity, and level of operation. This means that the precise nature of how these services will be provided, and the pricing attributable to them will not be confirmed until the Formal Agreement to Collaborate is entered into between the Parties
Establishment Input Contributions*	Establishment Input Contributions are set out in paragraph 7 of the Establishment Input Contributions Statement entered into by the Parties setting out the Parties' activities with respect to the On-boarding Project. The Establishment Input Contributions Statement is included in Schedule 6 .

* Note that these costs are subject to a [**] and capital charge, per Clause 8.1

SCHEDULE 4

Catapult Background Intellectual Property

[**]

SCHEDULE 5

Code of Conduct

Both Parties agree to:

- (a) Operate in a manner consistent with EU GMP to maintain a compliant multiproduct environment;
- (b) Operate in the spirit of the Collaboration;
- (c) Respect the confidentiality, privacy and operations of collaborators;
- (d) Wherever possible utilise the common infrastructure offered by the collection of cell and gene therapy related organisations in the local area, and nationally (the “**Cluster**”) in order to increase the benefits of the collaboration, and augment Cluster development, including the development of infrastructure connected with the Cluster;
- (e) Adhere to facility quality policies and protocol;
- (f) Adhere to roles and responsibilities as detailed in the Quality Technical Agreement and this Agreement; and
- (g) operate in compliance with all appropriate environment, health and safety requirements (both national and local).

COLLABORATOR also agrees to:

- (i) Maintain an environment within its Module in accordance with any procedures governing the Centre’s operation and the terms of occupation as stipulated in this Agreement and the QTA; and
- (ii) Abide by reasonable incident reporting requirements communicated by Catapult.

SCHEDULE 6

New Business Introduction and On-boarding

Introduction

1. The Catapult is committed to providing excellence in new business introduction for our collaborators. The following objectives underpin the Catapult's new business introduction philosophy:
 - (a) to guarantee that new business is introduced in accordance with our collaborators' expectations;
 - (b) to manage the new business introduction process to add value for our collaborators and for Catapult;
 - (c) to ensure that new business introductions meet the requirements of the Catapult Quality and EHS policies;
 - (d) to be open, honest and accurate in all of our new business introduction communications; and
 - (e) to develop excellence in our employees through the development of world class Project Management skills.
2. The new business introduction process for the Centre is divided into (i) a selection process, (ii) a negotiation phase on a Heads of Terms basis and a subsequent Collaboration Agreement and (iii) the On-boarding phase. The flow chart at the bottom of this schedule gives an overview of the different phases.

Summary of the Selection process

The new business introduction process starts with the Interest of a potential new collaborator in joining the Centre. After signing a CDA (Confidential Disclosure Agreement) Catapult will provide the COLLABORATOR with a 'Pre-screen questionnaire' to fill in. This document should allow Catapult to assess if the company and the planned manufactured product(s) will meet the requirements of the Centre's standards. The process should ensure a smooth transition to the negotiation phase on the Collaboration Agreement from a quality and operational perspective.

The Establishment Input Contributions Statement

The following Establishment Input Contributions Statement was entered into prior to signature of this Collaboration Agreement between COLLABORATOR and Catapult setting out the required Establishment Inputs and associated Contributions required to establish the GMP manufacture of cell and gene therapy medicinal products at the Centre:

ESTABLISHMENT INPUT CONTRIBUTIONS STATEMENT

Between:

- (1) **Freeline Therapeutics Limited** a company incorporated and registered in England & Wales with company number 09500073 and whose registered office is at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, SG1 2FX (“**COLLABORATOR**”); and
- (2) **Cell Therapy Catapult Limited**, trading as Cell and Gene Therapy Catapult, a company incorporated and registered in England & Wales with company number 07964711 whose registered office is at 12th Floor Tower Wing B, Guys Hospital, Great Maze Pond, London, SE1 9RT, United Kingdom (“**Catapult**”)

Date: _____

1. BACKGROUND

This Statement refers to the Collaboration Agreement to be entered into between COLLABORATOR and Catapult (“**Collaboration Agreement**”) in respect of the project to establish the GMP manufacture of cell and gene therapy medicinal products at the Cell and Gene Therapy Catapult Manufacturing Centre, Gunnels Wood Road, Stevenage, Herts SG1 2FX, United Kingdom (“**Centre**”). Unless explained otherwise, capitalised terms used in this Statement have the meanings given in the Collaboration Agreement from the date it is executed by the parties and becomes effective.

This Statement sets out the activities to be performed by both COLLABORATOR and Catapult to support the set-up of COLLABORATOR’S manufacturing processes and products at the Centre (“**On-boarding Project**”). These activities form part of the Establishment Inputs referred to in the Collaboration Agreement.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

The Contributions due from COLLABORATOR in relation to the **On-boarding Project** are set out in **paragraph 7** below.

2. OVERVIEW

COLLABORATOR acknowledges that

- The activities comprising Work Package 1 may be identified, planned and agreed prior to the Actual Occupation Date and prior to COLLABORATOR and Catapult entering into the Collaboration Agreement (CA) and Quality Technical Agreement (QTA). This will include providing the On-boarding documentation package to COLLABORATOR, reviewing the returned documentation and developing a detailed project plan, identifying any critical activities which are required such as facility modifications.
- Final execution and approval of the activities of Work Package 1 cannot take place until execution of the CA and QTA, at which point Catapult can establish COLLABORATOR within the Catapult quality system and raise a change control. COLLABORATOR can be established within the other IT systems and Catapult can apply for any required license updates plus commence any other activities that can take place prior to Module occupation,
- Those activities requiring Module occupation (operator training, gowning qualification and equipment installation) cannot take place until the after the Actual Occupation Date and execution of the CA and QTA. For the avoidance of doubt, the parties acknowledge that, depending on the timing of the Actual Occupation Date, the activities of Work Package 1 may continue following the Actual Occupation Date.
- There may be a short period of time (which will be defined during the On-boarding process) between the Actual Occupation Date and the point at which COLLABORATOR will be trained and qualified to enable them to take responsibility for Module cleaning and environmental monitoring. During this period, Catapult will retain responsible for this activity, with COLLABORATOR paying for consumables only (catapult gowning and environmental monitoring plates).
- Up until the date that the CA is executed by the parties, the term “Actual Occupation Date” when used in this Statement shall mean the date of COLLABORATOR’s occupation of the manufacturing space in COLLABORATOR’s Module in the Centre. Following the execution of the Collaboration Agreement, the term “Actual Occupation Date” shall have the meaning ascribed to it in the Collaboration Agreement.

3. WORK PACKAGE 1 – STANDARD ON-BOARDING PACKAGE

Administration and Control

The activity comprises a quality risk-based process that will be documented in the Centre’s Quality Management System following execution of the QTA. Catapult QA team will guide the process to ensure the GMP compliant Introduction of COLLABORATOR and its new manufacturing process into the Centre.

Project Management

The Standard On-boarding Package is led by a Catapult project manager, to a mutually agreed project schedule and a project plan determined by different work streams. It is anticipated that the majority of the Standard On-boarding Package will be performed prior to the Actual Occupation Date, except for operator training and gowning qualification plus equipment installation, which will take place after the Actual Occupation Date, however it may be the case that the Actual Occupation Date falls earlier in the Standard On-boarding Package.

Scope

On-boarding subject areas. Catapult will provide to COLLABORATOR the following Establishment Inputs:

- PROCESS – Process mapping, incorporating, where requested by COLLABORATOR, use of the HakObio software and virtual reality visualisation if required (managed by a Catapult Senior Scientist). Process mapping will identify:
 - optimised equipment layout and work flow in the manufacturing space (optional, if requested by COLLABORATOR)
 - initial and peak production estimates
 - material and equipment list
 - environmental monitoring, in-process and release testing requirements during a manufacturing run that require testing by Catapult
 - waste streams (large scale/small scale)

As part of the On-Boarding Project, including process mapping, COLLABORATOR will provide information relating to its product and manufacturing process only to the extent that the information materially relates to the anticipated interactions between COLLABORATOR and Catapult at the Centre. No other product or manufacturing process specific information will need to be provided to Catapult by COLLABORATOR.

- QUALITY CONTROL – Establishing COLLABORATOR analytical and environmental monitoring requirements. Establishing environmental monitoring framework within the LIMS software framework (It should be noted that the LIMS may not be available for configuration until January 2018) and training on the execution of routine environmental monitoring (managed by Catapult Quality Control)

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- ENVIRONMENTAL HEALTH & SAFETY – for example Genetically Modified Organism HSE update notification, trade effluent license changes (managed by the Catapult Health & Safety officer)
- MATERIALS and Product – Warehouse Management System set up (managed by the Catapult Warehouse and Logistic manager), including:
 - Entering and review of Raw Material Specifications into the warehouse management system
 - Location set up in the warehouse at different storage temperatures
 - Product storage schedule, including Cryohub relationship if applicable
 - Generation of bill of materials (BoMs)
- WASTE MANAGEMENT – set up of solid, liquid and clinical waste management system (managed by the Catapult Facilities management)
- EQUIPMENT – asset log, assessment and installation of equipment including linkage to the 24/7 monitoring/alarm system (to be agreed) (managed by the Catapult Facilities management)
- TRAINING – Centre Induction and basic GMP Training (managed by the Catapult Quality Assurance team) plus gowning qualification (managed by the Catapult QA & QC teams), for up to 6 operators
- FINANCE & IT – systems set up and training (managed by the Catapult IT manager)
- COMMUNICATIONS – Site Induction & Communications (managed by Catapult administrative staff)
- MANAGEMENT – Project management, QA oversight & governance and site senior management review process
- QUALITY ASSURANCE – Training in facility procedures, setting up the Master Control electronic Quality Management System (eQMS) roles and access rights, providing access to the supporting paper QMS

Additional Requirements

Additional COLLABORATOR requirements may be identified. These may include but will not be limited to: facility modifications, establishing systems for large volume waste inactivation and disposal and configuration of the LIMS for Additional QC Inputs or for connection of COLLABORATOR equipment. Such requirements will be managed by the Parties following the procedure governing Additional Inputs in the Collaboration Agreement.

4. WORK PACKAGE 2 – ON-BOARDING: MANUFACTURING SPACE QUALIFICATION

Catapult responsibilities

Catapult will perform an Operation Qualification (OQ) of the Manufacturing Space (as-built) prior to the Actual Occupation Date.

Catapult will define the minimum requirements for the at-rest OQ (Operation Qualification) and room PQ (Performance Qualification). Catapult will provide a template for the ‘at rest’ room OQ and room PQ protocols and reports for use by COLLABORATOR. Should COLLABORATOR elect not to use the Catapult templates, any templates proposed by COLLABORATOR must be approved in advance by Catapult.

Catapult will perform all analysis of the environmental monitoring outputs produced by COLLABORATOR according to the agreed study design, including specification if required.

Catapult will provide a final report of the environmental monitoring analysis.

The executed ‘at rest’ room OQ and room PQ reports will be approved by both COLLABORATOR and Catapult.

Catapult will provide all environmental monitoring consumables and 3 mobile volumetric air samplers and non-viable particle counters for use by COLLABORATOR for the initial manufacturing space qualification. Catapult will train COLLABORATOR in the relevant environmental monitoring sampling methods.

Collaborator responsibilities

COLLABORATOR is responsible for the execution of the ‘at rest’ OQ and PQ of its Module, in accordance with Catapult’s defined minimum requirements. This protocol will include environmental sampling within the Module and also a subcontracted Cleanroom Performance Study incorporating air pattern assessment employing smoke visualisation techniques, room clean-up rate assessment and non-viable particle analysis.

COLLABORATOR will perform the ‘at rest’ OQ and room PQ, the environmental monitoring sampling outputs being transferred to the Catapult for analysis.

Subcontractors

Cleanroom Performance testing will be performed by Clean Air Technology (CAT).

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Assumptions

Contributions (as set out in paragraph 6 below) are based on a standard study design, with a single performance of the OQ and PQ (incorporating a minimum of three separate sampling events). Study designs involving additional analysis or repetitions will incur additional Contributions to those set out in paragraph 6 below. Contributions Include no operator monitoring.

5. COOPERATION AND GOVERNANCE

Catapult and COLLABORATOR will work together to complete the On-boarding Project.

COLLABORATOR acknowledges that its regular input is key to the successful delivery of the On-boarding Project. Specific COLLABORATOR responsibilities are listed under Work Package 2 at paragraph 4 above.

Information will be shared by COLLABORATOR and Catapult and project plans will be generated and maintained during regular steering meetings attended by representatives of both COLLABORATOR and Catapult.

6. TIMEFRAME

It is estimated that (subject to COLLABORATOR making all necessary information available to Catapult and providing timely responses to enquiries from Catapult), the section of the Standard On-boarding Package which can occur prior to the Actual Occupation Date should commence approximately 6 to 8 weeks before the Actual Occupation Date. Following the Occupation Date, the remainder of the Standard On-boarding Package plus the On-boarding Manufacturing Space Qualification is expected be completed within 2 to 3 months following the Actual Occupation Date.

7. CONTRIBUTIONS

<u>Inputs</u>	<u>Contribution</u>
Work Package 1 Standard On-boarding Package	[**]
Work Package 2 On-boarding:	
Manufacturing Space Qualification	[**]
Subtotal:	[**]
[**] capital and risk charge	[**]
Total Input Contribution	[**]
Indicative consumable cost for WP1	[**]
Indicative consumable cost for WP2	[**]
Indicative subcontracting costs for WP2	[**]
TOTAL	[**]

All Contributions are subject to vat

- * Consumable prices are provided as an estimate and will be charged as a pass-through cost. Any significant variation from the estimate will be communicated to COLLABORATOR promptly.
- ** Subcontract costs will be passed directly to COLLABORATOR at the cost charged by the subcontractor.
- *** Contributions are subject to [**] Capital and Risk charge, which has been included above.

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The "Total Input Contribution" set out in this **paragraph 7** will be invoiced by Catapult on the Actual Occupation Date. Consumables and subcontracting costs will be invoiced as used. COLLABORATOR will pay accurate, complete and valid vat invoices within 30 days of receipt.

8. LIABILITY

[**] relation to the On-boarding Project shall be limited to [**]. In no circumstances shall Catapult or COLLABORATOR have any liability for any indirect, special or consequential loss or for any loss of profits, revenue, business opportunity, data, or goodwill (in each case whether such loss is direct or indirect). Nothing herein limits or excludes any person's liability to the extent that it may not be so limited or excluded by law, including any such liability for death or personal injury caused by that person's negligence, or liability for fraud or fraudulent misrepresentation.

Once and provided that COLLABORATOR and Catapult enter into the Collaboration Agreement then this **paragraph 8** shall be deemed deleted and replaced by the relevant provisions of the Collaboration Agreement with effect from the date the Collaboration Agreement takes effect in accordance with its terms.

9. TERMINATION

COLLABORATOR may, with or without cause, terminate this Statement with immediate effect on written notice to Catapult. Upon such termination, except as agreed to by Catapult and COLLABORATOR in writing, Catapult shall not undertake further work, or incur additional expenses or enter into further commitments, under this Statement. Following such termination, Catapult shall invoice COLLABORATOR, and COLLABORATOR shall pay for, all inputs properly performed, and consumables used under this Statement up to its termination, and non-cancellable subcontractor costs under this Statement. This **paragraph 9** shall survive termination of this Statement pursuant to **paragraph 9**.

This **paragraph 9** shall cease to have any effect on execution of the Collaboration Agreement by the parties.

10. CONFIDENTIALITY

Neither COLLABORATOR nor Catapult will make any further public disclosure relating to this Statement or the underlying work without the other's prior written consent.

Any confidential information supplied by either COLLABORATOR or Catapult in relation to this Statement will be subject (i) to the terms of the Confidentiality Agreement, dated 5 April 2013, entered into between COLLABORATOR and Catapult, before such time as the Collaboration Agreement is entered into by the parties, and then (ii) by the Collaboration Agreement, once it is executed by the parties.

AGREED by the parties through their duly authorised representatives on the date set out at the top of this Statement.

For and on behalf of:

Freeline Therapeutics Limited

Signed: _____

Name: _____

Position: _____

For and on behalf of:

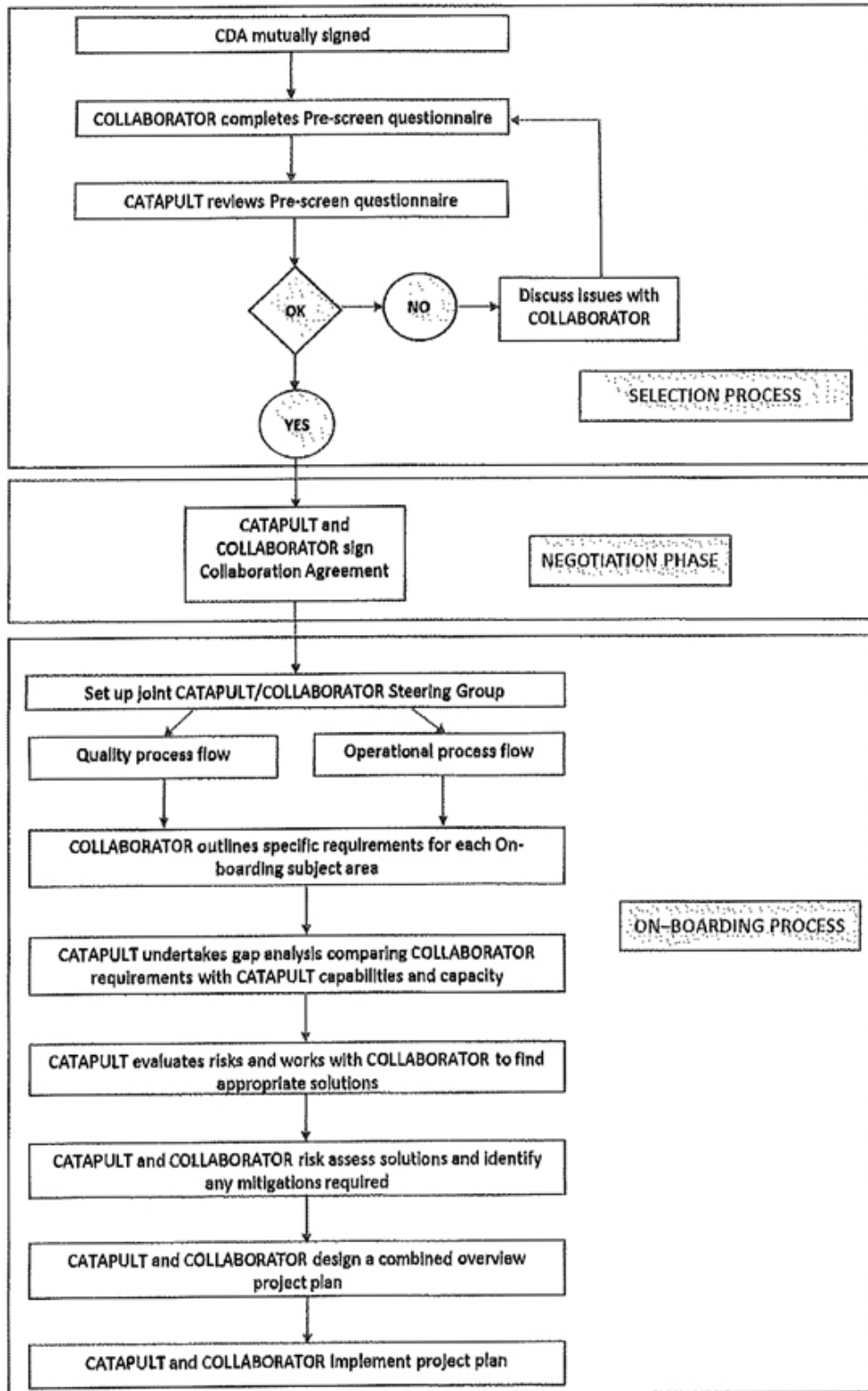
Cell Therapy Catapult Limited

Signed: [**] _____

Name: [**] _____

Position: CEO _____

New Business Introduction process flow: set out on the following page



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SCHEDULE 7

Schedule of Condition and Inventory of Module Fixtures and Fittings

To be provided under cover of a separate document, signed by both Parties immediately prior to occupation, but incorporated into this **Schedule 7** by reference.

SCHEDULE 8

Warehouse and Procurement Management Provisions

1. General

- 1.1 Catapult is responsible for operating the warehouse area & processes at the Centre in a GMP compliant manner. In summary this includes goods in, common consumables stock and COLLABORATOR owned stock, storage, picking, delivery and final product storage.
- 1.2 Catapult is responsible for the EHS within the warehouse and monitoring storage temperatures.
- 1.3 The Centre warehouse is an access controlled area limited to authorised Catapult personnel. COLLABORATOR personnel can only access the warehouse when accompanied by Catapult personnel.
- 1.4 Catapult will man the warehouse during business hours each week day (excluding bank holidays in England).
- 1.5 Catapult will provide a 24/7 call-out system for out of hours' deliveries, as an Additional input.
- 1.6 All COLLABORATOR equipment, samples and materials must enter the Centre through the Centre's goods in warehouse entrance. Samples and Materials will be booked onto the Catapult Warehouse management system.
- 1.7 Transfer to the Manufacturing Space of all COLLABORATOR equipment, samples and materials must be formally authorised by Catapult personnel.
- 1.8 The Centre is considered a forward picking area and as such warehouse space is limited.
 - (i) Catapult will maintain e stock of common consumables.
 - (ii) Each collaborator will have allocated storage at ambient temperature (15°C to 25°C), 2-8oC, -20oC, -80oC, and LN2 for their raw materials, product contact equipment, drug product, references and standards, and excipients. Catapult will be responsible for the qualification (IQ and OQ plus equipment-specific PQ with the units under load), monitoring, maintenance and functioning of the storage equipment and areas. Any COLLABORATOR-specific PQ will be an Additional Input.
 - (iii) Visibility of the COLLABORATOR's inventory is through the warehouse management system (Initially a paper based system). Each collaborator will only have visibility of their inventory items.

2. Warehouse Space

COLLABORATOR will be allocated a minimum amount of storage within the Centre's warehouse shown in the plans at Schedule 4 [**]

[**]

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- 2.2 Subsequent to occupation of modules in Phase 2 of the Centre, the minimum storage allocation above within the Centre's warehouse shown in the plans at **Schedule 4** will be halved, with the only exception to this being [**]
- 2.3 Catapult undertakes to provide and manage, at the COLLABORATOR'S expense, additional warehouse space suitable for the operation of GMP manufacture. Catapult agrees to implement this development in consultation with COLLABORATOR and agrees not to implement this Additional input without agreement of COLLABORATOR to its design and costs. Subject to timely COLLABORATOR agreement to the design and costs Catapult undertakes to use reasonable efforts to have the additional warehouse space available before commencement of Phase 2. Where the additional warehouse space is agreed in the Operational Forum as an additional Integral Input it will be paid for through the Integral Input Contribution. Where the Operational Forum does not agree it to be an Integral Input, the cost will be equitably split among the collaborators benefitting from it and paid for as an Additional Input Contribution.

3. Common consumables stock

- 3.1 CATAPULT will maintain a stock of an agreed list of commonly used consumables.
- 3.2 CATAPULT will be responsible for purchasing this stock, determining minimum stock levels required by collaborators, maintaining stock levels, undertaking the appropriate QC & putting the stock away.
- 3.3 CATAPULT will invoice the COLLABORATOR for the stock used by COLLABORATOR.
- 3.4 CATAPULT personnel will transfer the consumables to the COLLABORATOR's Grade C MAL staging area once a day or as agreed.
- 3.5 Common consumables stock will not be segregated between Collaborators and COLLABORATOR.

4. COLLABORATOR owned inventory

- 4.1 COLLABORATOR is responsible for the management of its own inventory supply chain including sourcing and auditing suppliers, price negotiation, purchasing and insurance.
- 4.2 Before purchasing any stock to be stored in the Centre, COLLABORATOR is responsible for providing a list of the inventory they will store and use within the Centre. Catapult reserves the right to reject any Inventory Item that is not in compliance with CATAPULT policies & procedures e.g. EHS.
- 4.3 COLLABORATOR is responsible for the completion & submission of a material specification for each item which will include such information as product container size, weight, required stock level, minimum stock level, QC sampling and testing regime.
- 4.4 Catapult will be responsible for notifying COLLABORATOR when the stock has reached its minimum stock level. The stock may then be re-ordered by COLLABORATOR.
- 4.5 COLLABORATOR must give at least 48 hours' notice of a delivery of their items, and must be delivered during the warehouse opening hours unless by prior agreement.
- 4.6 Catapult personnel will book the goods into the Warehouse management system, attach appropriate labels, undertake the initial goods inspection, notify COLLABORATOR of the goods receipt (and promptly notify COLLABORATOR of any issues identified on initial goods inspection) and place the goods in a location. Catapult will store COLLABORATOR inventory in a separate location from that of other Collaborators.
- 4.7 Catapult will make available storage (including LN2 storage) for retention samples, for which COLLABORATOR is responsible for the management of all of COLLABORATOR's retention samples stored by Catapult. Storage of retention samples for longer than 30 days will be available as an Additional Input.
- 4.8 COLLABORATOR will be responsible for the Quality Control (QC) of their inventory & pass labelling.
- 4.9 If the COLLABORATOR's products fail QC then COLLABORATOR personnel will be responsible for attaching reject labels, CATAPULT personnel will transfer these reject products to the relevant Reject product storage area. CATAPULT will store these Reject products for up to 30 days during which time it is expected that the COLLABORATOR will arrange appropriate disposal. If this is not arranged CATAPULT will manage the appropriate disposal with additional costs being charged to the COLLABORATOR.

5. Picking & delivery of stock for collaborators

- 5.1 For non-batch related common consumables stock such as clean room clothing Catapult manage the supply of these items.
- 5.2 For batch specific common consumables and for COLLABORATOR owned materials, COLLABORATOR will provide Catapult with a Bill of Materials (BoM) and a schedule identifying when the full or part BoMs are required.
- 5.3 A member of the COLLABORATOR staff will formally receive the BoM. If there are any queries or discrepancies with the BoM these will be highlighted & addressed at this time.
- 5.4 For biological material or cold-stored items, through prior arrangement, the COLLABORATOR with a Catapult representative will pick and transfer these items to the Manufacturing Space.

6. Final product storage

- 6.1 The Centre will provide final product, and product intermediate, storage at the following temperatures:
 - 6.1.1 -20°C
 - 6.1.2 -80°C
 - 6.1.3 LN2
 - 6.1.4 Controlled rate freezerRejected material will be stored in a segregated, multi-collaborator quarantine area in -80°C and LN2 storage.
- 6.2 The final product (or any intermediate thereof as requested by COLLABORATOR) will be stored in multi-collaborator storage equipment.
- 6.3 COLLABORATOR can store final product (or any intermediate thereof as requested by COLLABORATOR) in these storage areas for up to 44 days (and occasionally for additional periods by agreement with Catapult, at Catapult's discretion)
- 6.4 Access to the product storage areas will be strictly controlled and will only be possible when accompanied by an appropriately trained and authorised Catapult representative.
- 6.5 Catapult will be responsible for the qualification and maintenance of all equipment in this area including the temperature monitoring system and 24/7 emergency cover.

7. Drug substance (DS) or drug product (DP) (or product intermediate) packing area

- 7.1 Catapult will provide either a supervised GMP packing area or perform GMP packing.
- 7.2 Catapult will provide an area to charge dry shippers with liquid nitrogen.
- 7.3 Catapult will provide storage area for a reasonable supply of packing materials and boxes.

8. Drug substance (DS) or drug product (DP) (or product intermediate) shipping

- 8.1 If required by COLLABORATOR Catapult will provide access to cold chain GMP compliant courier service.

9. Examples of the warehouse & logistics additional services, available as Additional Inputs which are not included within Integral or Activity Related Inputs

- 9.1 Out of hours support.

- 9.2 Sampling of COLLABORATOR raw materials.
- 9.3 QC analysis of COLLABORATOR raw materials.
- 9.4 Auditing the COLLABORATOR supply chain.
- 9.5 Purchasing the COLLABORATOR raw materials.
- 9.6 Storing COLLABORATOR raw materials or starting materials for longer than the specified period.
- 9.7 Managing and storing retention samples.
- 9.8 GMP packing.
- 9.9 Arranging GMP shipping service through a GMP compliant logistics service provider.
- 9.10 Offsite additional storage space.

SCHEDULE 9

Environmental Monitoring Schedule

Introduction

Catapult is committed to providing and maintaining manufacturing and manufacturing support environments that are fit for their intended purpose with regard to air quality. These environments will be appropriately controlled and monitored based on the room classification requirements defined in Eudralex Volume 4 Annex 1. This will be achieved by:

- The regular application of qualified cleaning procedures to all GMP environments within the Centre.
- The training and qualification of personnel to assure the consistent and appropriate execution of gowning and de-gowning procedures.
- The development of and adherence to an appropriate environmental monitoring program.
- Regular reporting and trending of data generated by the program of Centre EM monitoring.
- The creation and dissemination of procedures for the appropriate handling of starting materials, raw materials, consumables, samples, In-process and final product and waste within the manufacturing facility.

Summary of the environmental monitoring process

- The environmental monitoring (EM) program shall be established by Catapult to comply with the requirements of Eudralex Volume 4 Annex 1 – Manufacture of sterile medicinal products.
- Catapult Quality will establish and periodically reassess (based on historical data) action and alert limits for EM test result values or all types of monitoring.
- Catapult will supply and perform routine calibration and servicing of the following calibrated EM sampling and measuring equipment per module for COLLABORATOR use, unless COLLABORATOR elects to employ their own monitoring equipment within isolators.
 - 3 portable active air samplers (for ‘in-operation’ viable air monitoring).
 - 3 portable non-viable particulate monitors.
 - 5 fixed sampling points and associated non-viable particulate monitors.
- Catapult will maintain a stock in the Catapult warehouse of all necessary consumables to facilitate collaborators to undertake viable ‘in-operation’ environmental monitoring (including sufficient TSA & SDA settle plates and contact plates to cover monitoring of the entire daily processing period).
- Responsibility for the execution of the Centre environmental monitoring program will be shared between Catapult and the collaborators per the QTA.
- When an order is placed by COLLABORATOR, Catapult Technical Services staff are responsible for the delivery of EM consumables to the relevant Materials Air Lock of the COLLABORATOR’S Manufacturing Space.
- COLLABORATOR collected EM samples should be appropriately labelled and packaged Immediately subsequent to exposure.
- When requested by COLLABORATOR staff, Catapult Technical Services staff are responsible for the collection of exposed EM samples from the PrAL, their transportation to Catapult QC Microbiology, documentation of their receipt and transfer to QC staff for storage prior to testing.

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- Catapult QC Microbiology staff are responsible for the appropriate processing of EM samples (incubation, enumeration and speciation as required), documenting the results and providing trended data to COLLABORATOR.
- All Manufacturing Space specific EM data and that collected from sampling of the common Centre areas will be made available to individual collaborators.
- Data will be presented per specific EM session and as a trend graph on a mutually agreed frequency. Data will include the results of any speciation undertaken as a result of an action or alert limit breach.
- Alert limit breach trends and any action limit breaches will result in Catapult QC staff raising a record in the Quality Management System to document the event, investigate root cause (with COLLABORATOR assistance if appropriate) and identify the appropriate preventative and corrective actions necessary to mitigate the risk of recurrence.

SCHEDULE 10

IT Infrastructure

The Centre will accommodate several collaborators consecutively, each of whom could potentially use the Centre in a different way.

The underlying IT infrastructure has been configured for each Module to have its own self-contained secure network. This will allow independent network scenarios, the configuration of these requirements will be carried out, administered and monitored by Catapult IT staff.

COLLABORATOR will have its own dedicated secure virtual local areas networks (VLANs).

All collaborators will however be subject to the Catapult's Information security policy.

Internet provision is not provided as standard however we can provide the following:

- Synchronous fibre broadband provided by Catapult at current market rates.
- COLLABORATOR supplies their own internet connectivity subject to wayleave.
- COLLABORATOR can also organise their own lease Line (PPTP) connectivity between their own sites and the Centre, subject to wayleave.

Server Infrastructure can also be provided by Catapult, the options that are available are as follows:

- Physical server on premises – this will be located in one of the Centre's communications rooms with restricted access (all access will be accompanied by Catapult IT staff)
- Virtual server on premises – this will be located on the Catapult virtual environment, remote access will be provided to the COLLABORATOR – SSL VPNs will be provided for access from external sites.
- Virtual server in private cloud – this will be located on Catapult's own private cloud, remote access will be provided to the COLLABORATOR – SSL VPNs will be provided for access from external sites.

If COLLABORATOR does not wish to use the options above, Catapult may offer, subject to availability and feasibility, the following option: physical/virtual server on COLLABORATOR's own site – A SSL site to site tunnel will be provided, access controlled by dedicated virtual local area networks VLANs.

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SCHEDULE 11

(NOT USED)

SCHEDULE 12

Module and Centre Specifications

1. Part A: Manufacturing Space Specification

It will:

- (a) be part of a GMP-compliant facility developed in close relationship with, and licensed by, the Medicines and Healthcare Products Regulatory Agency;
- (b) be of a design, construction, fit and finish in compliance with governing environment health and safety legislation;
- (c) be designed, and built fitted and finished in compliance with Applicable Law including 2001/83/EC and 2001/20/EC;
- (d) have individual personnel access control;
- (e) include a positive pressure maintained cleanroom with production area of not less than 86m² and a culture room of not less than 15m²;
- (f) have appropriate pressure cascades with negative pressure sinks in all entry and exit routes to minimise the risk of ingress and/or egress of contamination;
- (g) have walk-on ceilings and a technical corridor;
- (h) have a high-efficiency particulate arrestance (“HEPA”) filtered HVAC supplying segregated air as single pass through, with heat recovery;
- (i) have a gas supply delivered through services plates (details of the service plates are set out in Schedule 7);
- (j) have single and three phase power supply, partly with UPS and emergency generator back-up, supplied through service plates (details of the service plates are set out in Schedule 7); and
- (k) have dedicated adjacent material air locks (“MALs”), dedicated adjacent personnel air locks (“PALs”).

2. Part B: Manufacturing Office and Non-Manufacturing Office Specification

- (a) one Manufacturing Office of not less than 15m² as set out in the Plans with direct access from the controlled, non-classified corridor and designed for occupation by 4 people;
- (b) one Non-Manufacturing Office of not less than 28m² on the first or second floor of the Centre, as set out in the Plans and designed for occupation by 2 people;
- (c) Both of these offices will;
 - (i) be equipped for normal administrative functions only;
 - (ii) be equipped with lighting in line with British standards;
 - (iii) have lockable doors compliant with insurers requirements;
 - (iv) be furnished with desks, chairs and storage as agreed with the Centre staff, to accommodate the number of occupants they are designed to house;
 - (v) have small power outlets suitable for normal small office equipment use. The electricity usage will be measured and recharged as appropriate;

- (vi) have service media outlets for IT and Telephones. Internet services can be provided on request and recharged as appropriate as an Activity Related Contribution;
- (vii) a telephone for communication with Catapult. Outgoing calls will be charged at the service provider's rate; and
- (d) be heated and cooled from the central Centre systems. Temperature control will be only via the Building Management System (BMS) under the control of Catapult.

3. Part C: Centre Specifications

Facilities will include:

- (a) a warehouse packing and dispatch area; operated in accordance with **Schedule 8**;
- (b) a solid waste staging area;
- (c) a liquid waste staging disposal area;
- (d) male and female changing areas to access the controlled non classified (CNC) corridor;
- (e) PALs in and MALs in to access the grade C corridor;
- (f) PrALs to access the CNC corridor;
- (g) PALs out and MALs out to access the CNC corridor;
- (h) a reception area;
- (i) a rest/kitchen area
- (j) a meeting room for COLLABORATOR use; and
- (k) parking as set out in **Schedule 2, Part 2A**

SCHEDULE 13

Expert Determination

EXPERT

1. An Independent “Expert” is a person appointed in accordance with this **Schedule 13** to resolve a disagreement under **Clause 26.2** in connection with a change to the schedules listed at that Clause.
2. The Parties shall agree on the appointment of an Independent Expert and shall agree with the Expert the terms of their appointment.
3. If the Parties are unable to agree on an Expert or the terms of their appointment within 7 days of either Party serving details of a suggested expert on the other, either Party shall then be entitled to request the Centre for Effective Dispute Resolution (CEDR) to appoint an Expert of professional repute and for the CEDR to agree with the Expert the terms of appointment.
4. The Expert is required to prepare a written decision including reasons and give notice (including a copy) of the decision to the Parties within a maximum of 3 months of the matter being referred to the Expert.
5. If the Expert dies or becomes unwilling or incapable of acting, or does not deliver the decision within the time required by this **Schedule 13** then:
 - (a) either Party may apply to the London Court of International Arbitration to discharge the Expert and to appoint a replacement Expert with the required expertise; and
 - (b) this **Schedule 13** shall apply to the new Expert as if they were the first Expert appointed.
6. All matters under this **Schedule 13** must be conducted, and the Expert’s decision shall be written, in the English language.
7. The Parties are entitled to make submissions to the Expert including oral submissions and will provide (or procure that others provide) the Expert with such assistance and documents as the Expert reasonably requires for the purpose of reaching a decision.
8. Each Party shall with reasonable promptness supply each other with all information and give each other access to all documentation and personnel and/or things as the other Party may reasonably require to make a submission under this Schedule.
9. The Expert shall act as an expert and not as an arbitrator. The Expert shall determine the matter under this Agreement. The Expert’s written decision on the matters referred to them shall be final and binding on the Parties in the absence of manifest error or fraud.
10. The Expert’s fees and any costs properly incurred by them in arriving at their determination (including any fees and costs of any advisers appointed by the Expert) shall be borne by the Parties equally or in such other proportions as the Expert shall direct.
11. All matters concerning the process and result of the determination by the Expert shall be kept confidential among the Parties and the Expert.
12. Each Party shall act reasonably and co-operate to give effect to the provisions of this Schedule and otherwise do nothing to hinder or prevent the Expert from reaching their determination.
13. The Expert and CEDR shall have no liability to the Parties for any act or omission in relation to this appointment; save in the case of bad faith.

SCHEDULE 14

List of Centre Utilities

<u>Utility</u>	<u>Provider</u>
Natural Gas	Natural Grid (Supply) Npower (Meter and Usage)
Electricity	UK Power Networks (Supply and Infrastructure) Npower (Meter and Usage)
Water	Affinity (Supply)
Sewage	Thames Water(Supply)

SCHEDULE 15

Collaborator Forums

The purposes of the collaborator forums (the “Forums” or “Collaborator Forums”) are:

- to facilitate open and transparent exchange of Information between Catapult and collaborators, and between collaborators;
- to enable all parties to contribute to the safe, efficient, and successful operation of the Centre, and of the collaborators’ manufacturing activity, and
- to enable the standards of the centre to be maintained at an appropriate cost.

The Forums will be supplemented by regular informal ad-hoc meetings and weekly/bi-weekly surgeries involving Catapult and any collaborator as is necessary.

1. Key objectives of the Forums include:

- (a) updating any requirements needed to continue to maintain a suitable level of services for operation of a licensed facility suitable for late stage clinical and commercial manufacture of ATMPs in the most economical way;
 - (b) considering collaborator input into the relevant aspects of the management and operation of the Centre;
 - (c) ensuring Catapult and collaborator compliance with all relevant Quality, Health & Safety and legal requirements;
 - (d) discussing any modifications to any module or the Centre with the potential to impact any collaborator (prior to being raised in the relevant Forum, Catapult will consider all collaborator requests for facility modifications that require any other collaborator’s manufacturing space to be non-operational for any period of time, or that affect the Centre license and will discuss feasibility with the all collaborators. For clarity, such modifications should remain part of the notification to collaborators of the agenda for any Collaborator Forum);
 - (e) having formal two-way communications between Catapult and collaborators to discuss common issues;
 - (f) raising awareness of issues and incidents with potential for impact on the Catapult and collaborators;
 - (g) encouraging and facilitating the sharing of best practice between collaborators; and
 - (h) examining appropriate ways of managing costs.
2. The Forums will be advisory in their nature and initially take place monthly, with their frequency being reviewed/varied as required. However, the frequency of Forums will be no less than quarterly.
 3. The agenda, format, time and venue will be set and reasonable notice given in advance by Catapult, with the agenda being subject to change based on operational experience and input from collaborators.
 4. Relevant issues will be discussed and appropriate recommendations made during the Forums. Outputs of any key decisions that need to be made separately outside of the Forums will be communicated prior to the following meeting.
 5. Key issues and follow-up actions will be summarised and circulated to all collaborators by Catapult after each Forum.
 6. Collaborators will be fully consulted prior to any key decisions being made. Subject to the terms of this Agreement, in recognition of the fact that the Catapult has overall responsibility for the operation of the Centre, Catapult reserves the right to make the final decision in the best interests of all collaborators and the Catapult regarding matters put before the Forums.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

7. There will be 3 Forums covering 3 key areas, with the relevant Catapult chairs, Catapult leads, and Terms of Reference being summarised in the table below.

The Forums will be separated into 3 key areas, with the relevant Catapult chairs, Catapult leads or their representatives, and Terms of Reference being summarised in the table below.

FORUM	CATAPULT CHAIR	CATAPULT LEAD	TERMS OF REFERENCE
Quality Forum	Director of Quality	Head of QA	<ul style="list-style-type: none"> • Environmental Monitoring Trends • Collective discussion of recent deviations or changes with a shared impact • Audit findings (internal and external) • Audit findings of shared Vendors • Regulatory Trends • Best Practise Information • Training Requirements • Updates to Facility Management Procedures • Updates to Foundation Documents • Quality Agreement Compliance
Health & Safety	Manufacturing Centre Director	H&S Representative	<ul style="list-style-type: none"> • Review of Catapult & collaborator accidents, Incidents and near misses since last meeting • Review of accident, incident and near miss trends • Review of collaborators' EHS concerns • Catapult H&S update as it relates to: <ul style="list-style-type: none"> • People • Facilities, offices & equipment • Facility modifications • Biological & chemical • Contractor management • Catapult Environmental update • New or updated EHS legislation
Operational Forum	Manufacturing Centre Director	Operations Lead(s)	<ul style="list-style-type: none"> • Summary of current key discussions in the Quality and H&S forum, to ensure that any business critical topics receive broad attention • Catapult general operational updates • Collaborator general operational updates • Area specific issues/updates <ul style="list-style-type: none"> • Welfare • Process • Equipment • Materials & Product • Waste Management • IT • Communications • Proposed Facility modifications – requirements and costs • Schedule for any planned shutdowns • People & Training • Budgetary and resource issues/updates <ul style="list-style-type: none"> • Proposed capital expenditure • Update on any expected changes in Integral, Activity Related Input Contributions and Additional Input Contributions • Staff resources

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SCHEDULE 16

ADDITIONAL INPUT AGREEMENT

This Additional Input Agreement number [**] is entered into between the Collaborator and Catapult in accordance with, and in relation to, the Collaboration Agreement entered between Collaborator and Catapult on [**].

Collaborator:	Freeline Therapeutics Ltd.	Collaborator's Manager:	
Catapult:	Cell Therapy Catapult Limited	Catapult's Manager:	
Date of this Additional Input Agreement:			

Additional Inputs Required:

[List all items required with description]

Changes to the Contributions associated with the changes to be made under this Additional Input Agreement (Including changes to invoicing provisions):

[Price list – For facility modifications, this may include contributions for project scoping and also [**] of the agreement value may be charged for Project Management. [**]% capital and risk and vat will also be charged]

Additional terms required as a result of the changes to be made under this Additional Input Agreement:

[Any additional terms, if different to those in the CA]

This **Additional Input Agreement** is accepted:

For and an behalf of:

Freeline Therapeutics Ltd.

Signed: _____

Full Name: _____

Job Title: _____

For and an behalf of:

Cell Therapy Catapult Limited

Signed: _____

Full Name: _____

Job Title: _____

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

For and on behalf of:
Freeline Therapeutics Ltd.

Signed: _____
Full Name: _____
Job Title: _____

For and on behalf of:
Cell Therapy Catapult Limited

Signed: _____
Full Name: _____
Job Title: _____

END OF DOCUMENT

SERVICE AGREEMENT
All Service Levels

THIS SERVICE AGREEMENT (this “Agreement”) is made and entered into as of the 14th of May, 2018, (the “Effective Date”), by and between Aldevron, LLC, a North Dakota Limited Liability Company, located at 4837 Amber Valley Parkway, Fargo, ND, 58104 with manufacturing facilities for GMP-Source™ and GMP services at 3233 15th Street South, Fargo, ND 58104, USA and 4055 41st Ave S, Fargo, ND 58104 (“ALDEVRON”), and Freeline Therapeutics Limited, a company incorporated in England, UK (Company No. 09500073), located at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, United Kingdom and its affiliates (“CLIENT”).

RECITALS

WHEREAS, ALDEVRON is in the business of developing, marketing, and selling plasmid, protein, recombinant viral vectors, and antibody related products and services;

WHEREAS, ALDEVRON AND CLIENT have previously entered into a Mutual Confidential Disclosure Agreement dated 18 July 2017; and

WHEREAS, CLIENT is in the business of drug development and wishes to engage ALDEVRON to support CLIENT’s development with the production and storage of plasmid (plasmid cell banks) for the CLIENTS use with their manufacture of therapeutic products owned by CLIENT using an rAAV vector; and

WHEREAS, CLIENT desires to purchase products and/or services from ALDEVRON, and ALDEVRON desires to supply products and/or services to CLIENT according to the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein, and of other good and valuable consideration, the receipt and sufficiency of which hereby are acknowledged, ALDEVRON and CLIENT hereby agree as follows:

1. Definitions.

- 1.1 “Attachments” shall mean Quality Agreements, pricing agreements, or other forms specific to the Services or Products ordered, in each case as agreed and executed by the parties and referred to and incorporated into the relevant Order.
- 1.2 “Client Materials” shall mean all materials provided by the CLIENT including Starting Material (as defined in Section 4.4).
- 1.3 “Order” shall have the meaning given in Section 2.3.
- 1.4 “Product(s)” shall mean those plasmid(s), plasmid cell banks, protein(s), recombinant viral vector(s), and antibody related product(s) ordered by the CLIENT, as described in the relevant Order.
- 1.5 “Quality Agreement” shall mean the written agreement for Quality requirements available with Aldevron’s GMP-Source or GMP service levels, as agreed and executed by the parties and referred to and incorporated into the relevant Order.
- 1.6 “Specification” shall mean the written specification as set out in the relevant Order for Services and/or Products requested by CLIENT, which may or may not include cell bank, bulk material, shipping, storage, or final fill services.

2. Supply.

- 2.1 **Services.** ALDEVRON will provide to CLIENT, and CLIENT will purchase from ALDEVRON, the services as described in one or more Orders entered into by the parties in accordance with Section 2.3 (the “Services”).
- 2.2 **Supply of Product(s).** ALDEVRON shall manufacture in accordance with the Specifications, and supply and deliver exclusively to CLIENT the Product(s) in accordance with the relevant Order and the terms and conditions set forth in this Agreement. Any minimum or other purchase obligations applicable under this Agreement are identified in the relevant Order incorporated herein by reference.

- 2.3 **Orders.** To place an order, CLIENT shall deliver to ALDEVRON either (a) a CLIENT Purchase Order referencing a valid ALDEVRON Quote or (b) a mutually signed and accepted Statement of Work (each an "Order"). Each CLIENT Purchase Order referencing a valid ALDEVRON Quote shall be deemed accepted by ALDEVRON upon receipt, subject to the terms and conditions of this Agreement. Each Order issued under this Agreement shall be governed by and deemed to incorporate the terms and conditions of this Agreement. To the extent of any conflict or inconsistency between the terms and conditions of an Order and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control. Each Order issued under this Agreement shall refer to and be deemed to incorporate any relevant Attachments. To the extent of any conflict or inconsistency between the terms and conditions of an Order and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control; provided however that in the case of any conflict between this Agreement and an applicable Quality Agreement, the Quality Agreement will govern in matters of quality and this Agreement will govern in matters of business, financial or legal nature. Orders are intended to describe, among other things, the Products and/or Services to be provided, the scope and specifications for such Products and/or Services, timelines, any specific Client Materials to be provided by CLIENT to ALDEVRON, deliverables to be provided by ALDEVRON to CLIENT, reporting requirements, fees and charges, and any assumptions which govern the provision of the Products or Services.
- 2.4 **Manufacture.** ALDEVRON shall perform Services for CLIENT in accordance with (a) this Agreement, (b) the relevant Order and Specification and (c) ALDEVRON's standard operating procedures for Research Grade and GMP-Source or GMP service levels as applicable and as defined in any applicable Quality Agreement.
- 2.5 **Notification.** In the event that a research grade production event fails to provide adequate quantity or quality of Product, ALDEVRON will contact the CLIENT; if at the GMP-Source or GMP service level CLIENT will be contacted in accordance with the applicable Quality Agreement.
- 2.6 **Shipping and Delivery.** CLIENT acknowledges that final shipping costs may vary from the estimate and additional reasonable shipping charges may apply. Unless otherwise agreed to by the parties, ALDEVRON shall deliver the Products using ALDEVRON's standard methods for packaging and shipping Products. Product shall be delivered to CLIENT on an ex-works basis from the Facility (Incoterms 2000) along with the relevant Certificate of Analysis. [Time for delivery of Product is of the essence.] Save in the event of a delay in delivery attributable to force majeure (as defined in Section 19 below), ALDEVRON shall use its best endeavours to deliver Product to the locations and at the time specified in the applicable Order, and shall promptly notify CLIENT in the event of any anticipated delay in delivery.
- 2.7 **Testing.** Unless otherwise requested, ALDEVRON shall test the Products to ensure compliance with the Specifications and will provide a Certificate of Analysis with the results of testing performed.
- 2.8 **Acceptance.** CLIENT shall have a period of twenty (20) days from the date of its receipt of shipment of finished Product to inspect the Certificate of Analysis and reject the corresponding shipment of Product for nonconformity with the Specifications. If CLIENT rejects such shipment, it shall promptly so notify ALDEVRON and the provisions of Section 6 below shall apply.
- 2.9 **Latent Defects.** If after accepting a shipment of finished product, CLIENT subsequently discovers latent material defects (including without limitation, nonconformance to the Specifications) not reasonably discoverable during the acceptance period set forth in Section 2.8 above, but no later than 90 days after receipt, CLIENT may revoke its acceptance of such shipment of product by giving written notice and disclosing the nature of any defects to ALDEVRON. In such event, such product shall be considered a nonconforming product to the extent latent material defects in fact are present, and the provisions of Section 6 shall apply.
- 2.10 **Modifications.** From time to time during the Term, either party may propose modifications to the Specifications, including, without limitation, modifications that may enhance the Product(s) performance, safety and reliability, or that may make it easier or more economical to manufacture the Product(s), or that otherwise may be an improvement thereof. Such proposals shall be made in writing describing the modification in reasonable detail.
- 2.10.1 Any such proposal by ALDEVRON shall also include a written estimate of the resulting change in the price, if any, for the Product(s) affected by such modification.
- 2.10.2 If ALDEVRON receives a proposal from CLIENT to modify the Specifications, ALDEVRON shall promptly provide CLIENT with a written estimate of the resulting change in the price, if any, for the Product(s) affected by such modification. ALDEVRON agrees to consider all proposals from CLIENT to modify the Specifications in good faith and to use its commercially reasonable efforts to accommodate each such request.

2.10.3 Any amendment of, or addendum to, the Specifications, and any other change to any provision of this Agreement or any exhibit attached hereto resulting from such modification to the Specifications shall be effective once agreed to in writing by an authorized representative of ALDEVRON and CLIENT prior to being implemented; provided, however that ALDEVRON shall not unreasonably withhold approval of any modification in the Specifications requested by CLIENT.

2.10.4 The Quality Agreement Change Control process (as set out in the applicable Quality Agreement) will be adhered to for approval prior to the implementation of changes governed by an applicable Quality Agreement.

2.11 Records. For GMP-Source and GMP service levels, ALDEVRON shall maintain complete and accurate records of the progress of the Services and production of the Products ("Records") and shall store such Records per Section 2.11 or in accordance with the applicable Quality Agreement. ALDEVRON shall use commercially reasonable efforts to ensure that (i) data and records created in the performance of Services hereunder are being generated using sound scientific techniques and processes; (ii) data created in the performance of Services hereunder is being contemporaneously recorded in accordance with good scientific practices; and (iii) data created in the performance of Services hereunder is being analyzed appropriately without bias in accordance with good scientific practices. Upon fourteen (14) days' notice, ALDEVRON shall make these records available at to CLIENT or its designee, or any relevant regulator for the purposes of assessing compliance with the terms of this Agreement.

2.12 Storage. ALDEVRON shall store (on CLIENT's behalf) at its facility where the Services are performed or the Product is produced (the "Facility") any GMP-Source and GMP service level Product for a maximum period of twelve (12) months from the date such Products are ready for delivery. ALDEVRON shall store Records for a period of two (2) years from the date such Products are ready for delivery. CLIENT shall arrange for any storage of Products or Records beyond the periods described above or shall promptly collect the same from the Facility at CLIENT's expense. No less than five (5) weeks prior to a storage expiration date, ALDEVRON shall notify CLIENT to arrange for continued storage at CLIENT's expense or make arrangements for the collection of the Products or Records. If at the end of the relevant storage period (or such longer time as may otherwise be agreed between the parties), the Product and/or Records have not been collected by CLIENT, ALDEVRON shall notify CLIENT of the outstanding collection and ALDEVRON shall be entitled to destroy such Product and Records sixty (60) days after such notice.

2.13 Audit. CLIENT (or CLIENT's nominee) shall have the right to audit ALDEVRON's facilities used in the performance of the Services and/or production of the Product under this Agreement or its processes used or relevant to the performance of the Services and/or production of the Product under this Agreement in accordance with the applicable Quality Agreement.

2.14 Additional Services. ALDEVRON may provide, from time to time, services for CLIENT that include, but are not limited to, project management and the management of third party vendors on behalf of CLIENT. Such work will be described by a mutually signed and accepted Statement of Work in accordance with Section 2.3.

3. Pricing and Payment.

3.1 Payment Details. Account details will appear on the CLIENT invoice. Payments can be mailed to the main address.

3.2 Payment Terms. ALDEVRON may issue invoices to CLIENT in the amounts and at the times set out in the applicable Order. Each such invoice shall be accompanied by details of the Products and/or Services to which it relates. Payment terms are Net Thirty (30) days from receipt of invoice; provided that if any portion of an invoice is disputed, then CLIENT shall pay the undisputed amounts and provide written notice of the disputed amounts and details of the dispute to ALDEVRON, and the parties shall negotiate in good faith with a view to resolving such dispute and the disputed amount shall not become due until resolution of the dispute. All prices are in US dollars. CLIENT is responsible for wire fees. Checks must be drawn on a US bank.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

- 3.3 **Pricing.** The price payable by CLIENT to ALDEVRON for each Product(s) and any other Services purchased during the Term is as set forth in the applicable Order. Additional reasonable shipping charges apply. Final shipping costs may vary from estimate.
- 3.4 **International Orders and Taxes.** Prices do not, and will not, include any governmental taxes (including, without limitation, sales, use, excise, withholding, consumption or other VAT), or duties imposed by governmental authorities that are applicable to the import or purchase of the Product(s), and CLIENT shall bear all such taxes and duties.

4. Confidentiality.

- 4.1 **Restrictions on Use and Disclosure of Confidential Information.** Any Confidential Information (as defined below) of a party disclosed to the other party shall: (i) be maintained by the receiving party in strict confidence using at least the same degree of care such party would use to protect its own Confidential Information (but in any event, using no less than a reasonable degree of care); (ii) not be disclosed, directly or indirectly, to any third party without the prior written consent of the other party; and (iii) not be used for any purpose other than, in the case of ALDEVRON as receiving party, performing its obligations under this Agreement, or in the case of CLIENT as receiving party, enjoying its rights under this Agreement; provided, however, that the parties may disclose Confidential Information to their respective employees, directors, advisors, consultants, affiliates and approved vendors reasonably requiring access to such information for the purposes of performing such party's obligations under this Agreement (and in the case of CLIENT as receiving party, enjoying its rights under this Agreement), so long as, prior to such disclosure, each such person: (a) is advised of his/her obligation under this Section 4.1; and (b) shall have entered into a written agreement with confidential disclosure restrictions, which are at least as restrictive as those restrictions contained in this Section. Each party shall be responsible for any breach of the terms and restrictions of this Section by its representatives.
- 4.2 **Definition of Confidential Information.** "Confidential Information," means all confidential, non-public or proprietary information that is disclosed or made available by one party to the other party in connection with this Agreement. All Confidential Information shall as far as possible be identified as confidential at the time of disclosure. Confidential Information may include, without limitation, any inventions, discoveries, improvements, developments, ideas, know-how, trade secrets, technical and non-technical data, specifications, formulae, compounds, formulations, assays, methods, processes, techniques, practices, procedures, manufacturing techniques, designs, works of authorship, trade names, logos and other intellectual property, whether or not patentable or protectable by copyright or trademark, business and product plans, research and development plans or results, and sales, marketing, financial and pricing information, in each case, whether disclosed or made available in visual, oral, written, electronic, graphic or any other form, including in the form of samples. Confidential Information includes all copies, reproductions, notes and repositories thereof or based thereon, whether in written, electronic, graphic or any other form, including in the form of samples. Confidential Information shall not include any information that:
- a. at the time of disclosure is/was generally available to the public; or
 - b. after disclosure becomes generally available to the public, except through breach of this Agreement by the receiving party or any person to whom the receiving party disclosed it; or
 - c. is/was already possessed by the receiving party, as evidenced by its written records, predating receipt thereof from the disclosing party, so long as the receiving party did not receive such information directly or indirectly from a third party under an obligation of confidentiality to the disclosing party; or
 - d. is/was independently developed by or on behalf of the receiving party, as evidenced by written records, without direct or indirect use of any Confidential Information of the disclosing party.
 - e. is disclosed to the receiving party in good faith by a third party who has an independent right to such subject matter and information.

The obligations of non-disclosure and non-use set forth shall not apply to the extent disclosure of Confidential Information is required by law; provided, however, that receiving party shall (to the extent it is legally permitted to do so) promptly provide the disclosing party with written notice of such legal requirement and shall cooperate with the disclosing party to seek and obtain a protective order or other appropriate remedy prior to the disclosure of such Confidential Information.

- 4.3 Return of Confidential Information.** All Confidential Information shall be promptly returned or destroyed upon request. Copies and reproductions of the other party's Confidential Information (in whatever form, including information stored on readable media) shall upon the written request of the other party, be destroyed. Notwithstanding the foregoing provisions of this Section, each party shall be entitled to retain one (1) copy of the other party's Confidential Information, subject to the obligations of non-disclosure and non-use set forth in this Section 4, for the sole purpose of administering its rights and obligations under this Agreement. Either party shall not be required to destroy or return Confidential Information of the other party which is securely stored in automated electronic backups. ALDEVRON shall not be required to return Confidential Information contained within ALDEVRON's batch records and/or laboratory notebooks (although for clarity the confidentiality obligations set out in this agreement shall continue to apply to such retained Confidential Information).
- 4.4 Client Materials.** Client Materials shall be used by ALDEVRON solely to provide Services under this Agreement. ALDEVRON shall not reverse engineer, disassemble or decompile any Client Materials. Title to all Client Materials shall remain with CLIENT. ALDEVRON shall provide safe and secure storage conditions for Client Materials and shall use reasonable care and precautions to protect Client Materials from loss, damage, or contamination. Unless ALDEVRON is requested to store in accordance with Section 2.11, Client Material may be destroyed by ALDEVRON. "Excess Material" means Products generated above ordered deliverable quantities. At CLIENT's request, ALDEVRON shall store, deliver or dispose of Excess Material in accordance with Section 2.11 (additional fees may apply). "Starting Material" means any tangible materials (including starting material, reference material or samples) provided to ALDEVRON by CLIENT hereunder and may be consumed in its entirety in the provision of the Services. Starting Materials and Excess Material shall be treated as CLIENT's Confidential Information.

5. Limited Warranty.

- 5.1 Performance.** ALDEVRON warrants that its Products and Services shall be performed in a good and workmanlike manner in accordance with its standard operating procedures and according to the terms of the relevant Order and this Agreement, in accordance with all applicable laws, regulations and guidelines of relevant governing bodies. ALDEVRON warrants that to its knowledge at the time of the Service, the Service for manufacture of Products does not infringe or misappropriate any Third Party patent or trade secret, and that no claims or actions of infringement or misappropriation have been made, brought or threatened by such Third Party and that it has all the necessary consent and licenses necessary in order to perform the Services. ALDEVRON shall perform the Services in accordance with the timelines set out in the applicable Order or if no timetable is specified, within a reasonable time.
- 5.2 Specifications.** ALDEVRON warrants that its Products and Services conform to the applicable Specifications. ALDEVRON further warrants that it will issue an accurate and complete Certificate of Analysis to CLIENT with each delivery of Product(s). "Certificate of Analysis" means a certificate issued by ALDEVRON that confirms that an individual batch of Product meets the applicable Specifications and which shall contain the results obtained from testing performed as part of quality control of an individual batch of Product.
- 5.3 Results.** CLIENT understands that ALDEVRON cannot guarantee that all Client Materials will be capable of amplification. ALDEVRON will use reasonable means to reproduce the Client Material. CLIENT understands that ALDEVRON cannot guarantee results and in some cases CLIENT will incur charges regardless of actual results. ALDEVRON's limited warranty is contingent upon complete and accurate information being submitted by the CLIENT as well as material submitted by the CLIENT that is not damaged, defective, or otherwise flawed.
- 5.4 Debarment.** ALDEVRON hereby represents and warrants that neither it, nor any of its employees, agents or contractors who will participate in the performance of the services hereunder or in any other work to be performed for or on behalf of CLIENT, have been, are currently, or are the subject of a proceeding that could lead to their or their employees or agents becoming a debarred individual or debarred entity.

6. **Exclusive Remedy.** In the event of a breach of warranty set forth in Section 5 or notification of defective Product pursuant to Sections 2.8 and 2.9, ALDEVRON shall, at its option and expense, promptly correct such breach without charge to CLIENT either by (1) a rework or reprocess of the non-conforming Product or re-performance of the non-conforming Service, provided that any such rework or reprocess or re-performance conforms to the Specification or (2) the manufacture of a new batch of the non-conforming Product. If ALDEVRON is unable to correct any such breach, then CLIENT shall be entitled to a full credit for the non-conforming Product or Service. In the case of non-conforming Product, the foregoing remedies shall be available to CLIENT, provided that the CLIENT notifies ALDEVRON of the breach within 20 days of Product receipt or within 90 days of Product receipt for latent defects.
7. **Claims and Returns.** ALDEVRON will not accept returned Products without prior authorization. To obtain return goods authorization or return manufacture authorization, please contact your ALDEVRON Client Relations representative.
8. **Disclaimer of Warranties and Limitation of Remedies.**

EXCEPT TO THE EXTENT EXPRESSLY PROVIDED HEREIN, THE PRODUCTS AND ALDEVRON'S SERVICES ARE PROVIDED TO CLIENT "AS IS" WITHOUT ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED AND WITHOUT ANY REPRESENTATION OR WARRANTY THAT THE USE OF THE PRODUCTS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHT OF ANY PARTY.

To the maximum extent permitted by law, (a) in no event shall either party be liable to the other party for any special, incidental or consequential damages, which may arise from or in connection with this Agreement or the use, handling or storage of the Products, and (b) each party's total liability under or in relation to this Agreement shall be limited to the amount paid and due to be paid by CLIENT to ALDEVRON under this Agreement.

9. **Indemnification.**

- 9.1 Subject to Sections 8 and 9.2, CLIENT agrees to indemnify ALDEVRON, its officers, directors, employees, affiliates, and agents ("ALDEVRON Indemnitees") against any claim, damage, or liability of any kind (including, but not limited to, any reasonable attorneys' fees, legal costs and expenses) suffered or incurred by an ALDEVRON Indemnitee in connection with any third party claim, demand, action or suit brought against an ALDEVRON Indemnitee arising out of: (i) the Client Materials or other samples sent to ALDEVRON by the CLIENT infringing any Intellectual Property Rights (as defined in Section 14.1 below) of any third party; (ii) a breach of any representation or covenant of CLIENT under this Agreement; or (iii) any other claim connected with any use, handling, or storage of the Products by CLIENT, except to the extent such occurrence arises from the breach of this Agreement by an ALDEVRON Indemnitee or the gross negligence or willful misconduct on the part of an ALDEVRON Indemnitee.
- 9.2 Subject to Sections 8 and 9.2, ALDEVRON agrees to indemnify CLIENT, its officers, directors, employees, affiliates, and agents ("CLIENT Indemnitees") against any claim, damage, or liability of any kind (including, but not limited to, any reasonable attorneys' fees, legal costs and expenses) suffered or incurred by a CLIENT Indemnitee in connection with any third party claim, demand, action or suit brought against a CLIENT Indemnitee arising out of: (i) the infringement by an ALDEVRON Indemnitee of the Intellectual Property Rights (as defined in Section 14.1 below) of any third party in the course of performance of the Services, except to the extent that such infringement arises specifically from the use of the Client Materials in accordance with this Agreement; or (ii) a breach of any representation or covenant of ALDEVRON under this Agreement, including the death or personal injury of any third party arising out of a breach of this Agreement by an ALDEVRON Indemnitee or the negligence or wrongful act of an ALDEVRON Indemnitee; except to the extent such occurrence arises from the breach of this Agreement by a CLIENT Indemnitee or the gross negligence or willful misconduct on the part of a CLIENT Indemnitee.
- 9.3 Where a person (the "Indemnified Party") seeks indemnification from the other party (the "Indemnifying Party") under this Agreement, the Indemnified Party shall provide prompt written notice to the Indemnifying Party of the assertion or commencement of any such third party claim, demand, action or suit. The Indemnifying Party shall have the right to assume the defense and/or settlement of the same and shall not be liable for any settlement made by the Indemnified Party without the Indemnifying Party's consent, provided that the Indemnifying Party may not use any defense or agree to any settlement that would materially prejudice the Indemnified Party. The Indemnified Party shall: (a) promptly provide all assistance and information reasonably required by the

Indemnifying Party; (b) not make any admission of liability, conclude any agreement or make any compromise with any person in relation to such claim, demand, action or suit without the prior written consent of the Indemnifying Party; and (c) have the right to participate in (but not control) the defence of the claim, demand, action or suit and to retain its own counsel in connection with such claim at its own expense.

10. **Outsourcing.** ALDEVRON may not sub-contract the performance of any part of the Services to any Affiliate or third party unless (a) the Order provides that such Services may be sub-contracted to such sub-contractor or (b) CLIENT has given its prior written consent (which may be withheld at the sole discretion of CLIENT). ALDEVRON provides only essential information to vendors and will protect CLIENT confidentiality as per Section 4 Confidentiality. For GMP- Source and GMP service levels, ALDEVRON shall utilize an approved vendor system that is managed by ALDEVRON's Quality System. ALDEVRON shall remain liable for the full and proper performance of all of its obligations under this Agreement and shall be responsible for the oversight of all permitted subcontractors and for any acts and omissions of any permitted subcontractor that would, if effected by ALDEVRON, constitute a breach of this Agreement.
11. **Compliance with Laws and Regulations.** ALDEVRON certifies that to the best of its knowledge: the Products are produced in compliance with all applicable federal, state, and local statutes, rules, regulations, and ordinances at the time of order.
12. **Authorized Uses.** CLIENT represents and warrants to ALDEVRON that: CLIENT will properly test, use, and, to the extent authorized, manufacture and market any Products purchased from ALDEVRON and any final articles made from them in accordance with and in compliance with all applicable federal, state, and local statutes, rules, regulations, ordinances, and orders.
13. **Governing Law.** This Agreement shall be governed and construed in accordance with the procedural and substantive laws of the state of New York. Any litigation, disputes, claims or proceedings between the Parties arising under this Agreement or in relation to any Services or products provided by ALDEVRON to CLIENT pursuant hereto shall be subject to the non-exclusive jurisdiction of the courts of the state of New York, and the parties expressly waive any objections as to venue in any such courts.
14. **Intellectual Property.**
 - 14.1 **Intellectual Property.** For purposes of this Agreement, the term "Intellectual Property Rights" means any and all rights, titles and interests, whether foreign or domestic, in and to any and all trade secrets, patents, copyrights, service marks, trademarks, know-how or similar intellectual property rights and similar rights of any type under the laws or regulations of any governmental, regulatory, or judicial authority, whether foreign or domestic.
 - 14.2 **CLIENT Property.** ALDEVRON hereby assigns to CLIENT all right, title, and interest in all concepts, inventions and improvements, whether or not copyrightable or patentable, relating to the Products, samples and test articles provided hereunder and/or discovered as a result of performing Services for CLIENT under the Agreement (collectively, the "Inventions"). ALDEVRON agrees, upon CLIENT's request and at CLIENT's expense, to do all things reasonably necessary to obtain patents or copyrights on any Inventions discovered exclusively as a result of performing CLIENT's Services and to execute any documents necessary to formalize the afore-mentioned assignments.
 - 14.3 **ALDEVRON Property.** Notwithstanding the foregoing, CLIENT acknowledges that ALDEVRON possesses certain inventions, processes, know-how, trade secrets, other intellectual property and assets, including but not limited to, [**] which have been independently developed by ALDEVRON (collectively, the "Aldevron Property"). CLIENT and ALDEVRON agree that any ALDEVRON Property, or improvements thereto which are used, improved, modified or developed by ALDEVRON under or during the term of this Agreement, and which do not require the use of any CLIENT Material or CLIENT Confidential Information are the product of ALDEVRON's technical expertise possessed, developed by ALDEVRON prior to or during the performance of this Agreement and are the sole and exclusive property of ALDEVRON. If and to the extent that CLIENT needs a license under any Intellectual Property Rights owned or controlled by ALDEVRON in order to exploit the Products and/or results of the Services, ALDEVRON hereby grants to CLIENT a non-exclusive, fully paid-up, perpetual, irrevocable, transferable, worldwide license (with the right to sub-license through multiple tiers) under such Intellectual Property Rights solely for the purpose of exploiting the Products and/or results of the Services.

- 14.4 Do Not Incorporate.** The receiving party shall not embody any of the Confidential Information of the disclosing party in any of the receiving party's products, processes or services, or duplicate or exploit any of such Confidential Information in the receiving party's business, or file any patent application, utility model or design application based upon, derived from any Confidential Information of the disclosing party or otherwise use any of the Confidential Information for any purpose other than for the permitted purpose of this Agreement.
- 14.5 Freedom to Operate.** CLIENT and ALDEVRON are free to develop products independently without the use of the other's Confidential Information.
- 15. Term & Termination.**
- 15.1 Agreement Term.** The term of this Agreement shall commence upon the Effective Date and shall, unless earlier terminated with at least ninety (90) days written notice, continue until the fifth (5) anniversary of the Effective Date, and shall automatically extend for additional one (1) year periods unless either party has given at least ninety (90) days written notice of its desire to terminate this Agreement. Provided that, unless otherwise provided in such notice, termination of the Agreement shall not result in termination of any uncompleted work, which shall continue under all terms of this Agreement until completion or termination. CLIENT shall pay for Product or Services ordered by CLIENT and properly provided by ALDEVRON pursuant to this Agreement prior to the effective date of termination in accordance with Section 3.
- 15.2 Termination for Breach or Insolvency.** This Agreement may be terminated immediately by either party by written notice to the other party upon:
- 15.2.5 the material breach of this Agreement by the other party and the failure of such other party to cure such breach within thirty (30) days of receipt of the non-breaching party's written notice of such breach; or
- 15.2.6 in the event that (i) the other party becomes insolvent or unable to pay its debts as and when they become due; or (ii) a petition is advertised an order is made or a resolution is passed or an order being made for: (a) for the winding up of the other party or (b) to appoint a liquidator, administrator, administrative receiver, receiver, or trustee, or any of the same are appointed in respect of or in connection with the liquidation, administration or dissolution of the other party or the whole or any part of the other party's assets or business; or (iii) the other party makes or proposes to make any composition or enters or proposes to enter into any other arrangements with or for the benefit of its creditors; or (iv) the other party ceases to continue its business or a substantial part of it or threatens to cease to continue its business or a substantial part of it; or (v) the other party takes or suffers any similar or analogous action in any jurisdiction. Each party shall immediately notify the other party in writing in the event that any of the foregoing events occur with respect to such party.
- 15.3 Confidentiality Term.** All Confidential Information shall be held confidential by the receiving party for seven (7) years from the date of expiry or termination of this Agreement ("Expiration"), provided, that with respect to trade secrets, such period shall be extended for so long as such trade secrets remain protected as such under applicable laws.
- 15.4 Other.** Furthermore, any term or provision of this Agreement that by its nature is intended to survive termination hereof will so survive and apply, including without limitation Section 14. All terms and provisions of this Agreement shall be binding on the parties and their respective successors and permitted assigns.

16. Miscellaneous

16.1 **Notices.** All notices hereunder shall be in writing and sent to the address below (i) personally; (ii) by registered or certified mail, postage prepaid, return receipt request; (iii) by overnight courier service; or (iv) by electronic copy with delivery confirmation from recipient; to the following recipients at the addresses of the respective parties:

ALDEVRON

Aldevron
4837 Amber Valley Parkway
Fargo, ND 58104
Attn: Contracts
e-mail: [**]
copy to: [**]
e-mail: [**]

CLIENT

Freeline Therapeutics Ltd
Stevenage Bioscience Catalyst,
Gunnels Wood Road, Stevenage, Herts, SG1 2FX
Attention [**]
e-mail: [**]
copy to: [**]
e-mail: [**]

Notices shall be effective upon receipt if personally delivered, on the fifth business day following the date of mailing if mailed, and upon receipt if sent by overnight courier service, or if sent by email, at 9.00 am on the next business day after transmission. A party may change its address listed above by written notice to the other party. The parties agree that any signature delivered by email or facsimile transmission shall have the same force and effect as an original signature.

16.2 **Headings.** The headings of the sections and subsections of this Agreement are intended solely for convenience and shall not be deemed to constitute part of this Agreement or to affect the construction or interpretation hereof.

16.3 **Severability.** In case any one or more of the provisions of this Agreement shall be held by a court with proper jurisdiction to be invalid, illegal, or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

16.4 **Waiver; Modification of Agreement.** No waiver, amendment or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both parties hereto. No modification to this Agreement shall be affected by the acknowledgment or acceptance of any purchase order, invoice or similar documents containing terms or conditions at variance with or in addition to those set forth herein. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

16.5 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original and all of which shall constitute one and the same Agreement. Facsimile signatures of any original document shall be considered the same as delivery of an original. Electronic signatures provided via an agreed upon electronic signature service shall be considered the same as delivery of a signed original.

16.6 **Contract Interpretation.** Ambiguities, inconsistencies or conflicts in this Agreement will not be strictly construed against either party, including the party regarded as the original drafter, but will be resolved by applying the most reasonable consideration to the parties' intentions at the time of this Agreement is entered into and common practice in the industry.

17. **Independent Parties.** Nothing in this Agreement, quotes, or other documentation shall be construed as to create any relationship between ALDEVRON and CLIENT other than that of independent contracting parties. Neither party shall have any right, power, or authority to assume create or incur any expense, liability, or obligation, express or implied, on behalf of the other.

18. **Mutual Insurance.** Each party shall procure and maintain in force for itself and its staff, professional liability coverage with policy limits of [**] per occurrence and [**] annual aggregate and general liability coverage with policy limits of [**] per occurrence and [**] annual aggregate. Such coverage shall be self-insured or underwritten by a reputable insurance organization authorized to do business in the state of each party's principal place of business. Upon request, each party will provide proof of its liability coverage to the other party.

19. **Force Majeure.** Neither party shall be liable or deemed to be in default for any delays due to causes beyond the reasonable control of the affected party such as war, civil disorders, acts of God, or governmental action (including regulatory restrictions or actions or regulatory agencies) not directly related to this Agreement, provided that the affected party promptly notifies the other of the causes and its effects on its performance under this Agreement.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

20. **Assignment.** Neither party shall have the right to assign its rights or obligations under this Agreement (whether by operation of law or otherwise) without the prior written consent of the other party; provided that CLIENT may, after having given prior written notice to ALDEVRON, assign all its rights and obligations under this Agreement to any person to which it transfers all or substantially all of its assets or business to which this Agreement relates. This Agreement shall not be extended to any other business or service.
21. **Entire Agreement.** This Agreement including the applicable Orders embodies the entire understanding of ALDEVRON and CLIENT in relation to its subject matter and there are no promises, terms, conditions or obligations, oral or written, expressed or implied, other than those contained in the Agreement, in relation to such subject matter. The terms of the Agreement shall supersede all previous agreements (if any) which may exist or have existed between ALDEVRON and CLIENT relating to the Services. The parties acknowledge that they have entered into a Mutual Confidential Disclosure Agreement dated 18 July 2017 (the "CDA") under which Confidential Information (as defined in the CDA) has been disclosed (the "Existing Information"). The parties agree that: (i) for the term of this Agreement, the Existing Information be deemed to be Confidential Information of the relevant party under this Agreement; (ii) the terms of this Agreement rather than the terms of the CDA shall govern the use of such information; and all information disclosed by the parties during the term of this Agreement shall be governed by this Agreement and shall not be governed by such Confidentiality Agreement. The Agreement may only be modified by a written agreement signed by duly authorized representatives of the parties.

[Signature follows]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

ALDEVRON

FREELINE THERAPEUTICS LIMITED

Signature:

Signature:

Name: [**]

Title: Director
Date: May 15, 2018

Name: [**]

Title: CEO
Date: May 17, 2018



Biopharma Services Agreement

[] *MCB & WCB manufacturing & release***

Date:

Sunday, June 05, 2016

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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NOVASEP General Information

NOVASEP provides bioprocess development and contract manufacturing services for most types of biologics, from pre-clinical supply to commercial manufacturing.

Our contract development and manufacturing strategy is made up of flexible modules covering the entire process chain from cell line development to formulation and fill & finish of your drug products.

Our mission is to bring process and product innovation to bioprocessing in order to support you in the development of your biomolecules from preclinical to commercial batches in the most efficient way.

We are able to provide turnkey services from gene to clinical product, including all banking; USP-DSP development; scale-up; formulation and fill & finish; QC development, validation and final release for clinical trials.

We work from your process or develop one from scratch, always sharing with you the know how, vision and realistic expectations. More than 15 years' experience and 200 projects have made this rare and recognized added value possible.

Our difference is the integration of our advanced technologies into bioprocessing and our ability to bring them to optimal performance through our process development capabilities. Then, depending on your manufacturing strategy, you are free to choose between in-sourcing our downstream processing technologies or out-sourcing production with us... or both!

Your benefits are numerous:

- Our experience with a broad range of expression systems as well as upstream and downstream technologies;
- An experienced CMO partner who is both an end-user and a provider of purification technologies;
- A unique organization capable of designing your process, as well as engineering, building, validating and operating the bio-manufacturing plant for your biologics;
- A complete staff dedicated to your process development;
- Great flexibility to match your timelines and contract management, and an ability to cope with quick process change needs, which are frequent in bioprocess development

NOVASEP offers you a unique combination of services and advanced technologies for producing and purifying your biopharmaceuticals, from laboratory to industrial scale:

- **Outsourcing solutions:** contract manufacturing services, from master cell bank to aseptic formulation, fill & finish and released drug product.

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- **In-sourcing solutions, for biologics manufacturing:** including our chromatography (**Prochrom® biochromatography column**) and Tangential Flow Filtration (TFF) solutions (**TangenX membranes, reusable and Sius single-use cassettes and TFF systems**), from lab to industrial scale

NOVASEP-Biopharma CMO capacities & equipment

NOVASEP offers capacities for biopharmaceuticals in Belgium and in France.

The three facilities are part of NOVASEP Biopharma Business Unit and are offering capacities for Research & Development, USP cGMP productions (Belgium only), DSP cGMP production and F&F (Belgium only).



Belgium - Gosselies

R&D Labs

USP

DSP

F&F

BSL 1-3



Belgium - Senefte

R&D Labs

USP

DSP

F&F

BSL 1-2



France - Pompey

R&D Labs

DSP

BSL1

The following industrial scenarios are implemented for the production in cell culture:

Reusable Bioreactors:

R&D – 2L* Applikon glass bioreactors

R&D/GMP – 10L* Applikon glass bioreactors

R&D – 60L* Applikon Stainless Steel bioreactor

GMP – 20L/80L/250L* - Guerin Stainless Steel train of bioreactors

Disposable/Single-use Bioreactors (SUB):

R&D/GMP – SUB 50L* BioStat STR Cultibag Sartorius

R&D/GMP – SUB 200L* BioStat STR Cultibag Sartorius

GMP 1,000L* - SUB BioStat STR CultiBag Sartorius

* Volumes are expressed as working volumes

The following equipments are available for the production of protein by micro-organisms (fermentation):

- 4* 2L* (Sartorius)

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- 1* 12L* (NewBrunswick)
- 1* 100L* (Sartorius)
- High Pressure homogenizers: Panda and Panther systems (Niro Soavi)
- Numerous incubators for culture in shake-flasks
- Culture harvest either by centrifugation and/or tangential flow filtration (hollow fibers)

* Volumes are expressed as working volumes.

Fill & Finish Capacities:

Formulation & Fill & Finish

- Development of aseptic processes
 - Filtration
 - Vialing processes
- Finish
 - Visual inspection
 - Clinical labelling
 - Secondary/tertiary packaging
 - Flash freezing
 - Final storage at all temperatures

F&F Capacities

- For non-viable and viable products until BSL3
- Sterile filtration of bulk product
 - Gosselies: up to 10L bulk (up to 550 vials, up to 2.5 mL/vial)
 - Seneffe: up to 50L bulk (up to 1500 vials/H, up to 100 mL/vial)
- Automated liquid filling machine FPC50 (Seneffe)
 - High recovery rates
 - Disposable product-contact surfaces
 - cGMP Aseptic filling of vials (manual and automatic)
 - Clean room background class B
- Operation in a grade A filling area (RABS or LAF)
 - MFT 19 batch sizes up to 4,000 3 mL-glass vials and 12L bulk volume
 - MFT 20 batch size 2,500 20 mL-glass vials and 50 L bulk volume
 - MFT 06 batch size 550 3ml-glass vials and 10L bulk volume
- Wide range of filling parameters and container closure configurations
 - 2 mL to 100 mL vials
 - 0.1 mL to 100 mL fill volume
- Validation of aseptic fills (> 20 MFT)
- Media fills performed with product-specific components
- Container-closure studies.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

This services agreement, hereafter referred to as the “**Agreement**”, is entered into on 2016 (the “Effective Date”), **by and between**

FREELINE THERAPEUTICS, a corporation having its company registered in England under number 9500073, having its registered address at 215 Euston Road, London, NW1 2BE and its principal place of business at at Freeline Therapeutics Limited, UCL Royal Free Medical School, Pond Street • London • NW3 2QG, The UK.

hereafter referred to as “**FREELINE THERAPEUTICS**” or “**CUSTOMER**”,

and

Henogen SA (a subsidiary of the NOVASEP group), a Belgian corporation having its registered address at 12 rue des Professeurs Jeener et Brachet, B-6041 Gosselies, BELGIUM,

hereafter referred as “**NOVASEP**”.

CUSTOMER and NOVASEP will be hereafter be referred to separately as “**the Party**” and jointly as “**the Parties**”.

WHEREAS:

(i) FREELINE THERAPEUTICS wishes to engage NOVASEP to conduct Work to manufacture a MCB and WCB from a [**] (“the Product”),

(ii) NOVASEP has the professional skills and knowledge to perform such Work on the terms and conditions set forth herein; in particular NOVASEP is an expert in cell culture, fermentation, synthesis, purification (including chromatography), sterile filtration and aseptic fill & finish processes;

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the adequacy of which is acknowledged by each of the Parties, the Parties hereto agree as follows:

Part 1: Definitions

In this Agreement, unless the context otherwise requires, the following expressions shall have the following meanings:

“**Affiliates**” means any company, corporation, firm, partnership or other entity which is directly or indirectly controlled by, or under the same control of any of the Parties, where control means the power, direct or indirect, to direct or cause the direction of the management and policies of such entity, whether by contract, through the by-laws of the aforementioned entities or otherwise;

“**Agreement**” means the present Agreement and all its Appendix(es);

“**Confidential Information**” means any and all commercial and technical information, including but not limited to documents, strategies, methods, procedures, know-how, trade secrets, pre-clinical and clinical test-data, or technical or marketing information regardless of method of storage, and copies thereof, disclosed by one Party (“the Disclosing Party”) to the other Party (“the Receiving Party”) pursuant to this Agreement and shall also include:

- (a) Customer Data, CUSTOMER’s products, and CUSTOMER’s manufacturing/production process or methods, which shall be deemed to be Confidential Information of CUSTOMER; and
- (b) Information regarding NOVASEP’s manufacturing/production process or methods, which shall be deemed to be Confidential Information of NOVASEP.

“**Customer Data**” means all data, Confidential Information, methods, substances, samples and Materials provided to NOVASEP by CUSTOMER pursuant to this Agreement;

“**Effective Date**” means the date mentioned on top of the first page of this Agreement;

“**Facility**” shall mean NOVASEP’s development and manufacturing facility(ies) where the Work will be carried out, as agreed between the parties;

“**Force Majeure**” has the meaning given in Section 13 of Part 4 of this Agreement;

“**Intellectual Property Rights**” has the meaning given in Section 5.1 of Part 4 of this Agreement;

“**Materials**” means materials, raw materials, compounds or intermediates supplied by CUSTOMER to NOVASEP under this Agreement;

“**NOVASEP Background Intellectual Property**” has the meaning given in Section 5.1 of Part 4 of this Agreement;

“**Product**” means the MCB and the WCB produced from a source [**] by FREELINE and supplied by NOVASEP as described in the present Agreement;

“**Results**” has the meaning given in Section 5.1 of this Agreement;


“**Work**” means the development work and services to be conducted by NOVASEP pursuant to this Agreement and as more particularly described in the Part 2; the Work will be divided in different stages (each a “Work Package”), as more precisely defined in Part 2 of this Agreement;


Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

“Written” or “in writing” form means either paper hardcopy or facsimile signed by both Parties or mail confirmed by both Parties.

[] MCB & WCB manufacturing & release**

Prepared for: [**]
Chief Development Officer
Freeline Therapeutics Limited
UCL Royal Free Medical School
Pond Street • London • NW3 2QG
 [**]
[**]

Prepared by: [**]
Strategic Project Director
 [**]
[**]

[**]
CMO Business Development
 [**]
[**]

Henogen SA - NOVASEP Belgium
12 rue des Professeurs Jeener et Brachet,
6041, Gosselies,
BELGIUM

Sales Contact [**]
Area Sales Manager
 [**]
[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

1. Introduction & Inquiry

Linked with the objective to produce [**] using transiently transfected [**], FREELINE THERAPEUTICS is looking for the manufacturing and release of a Master Cell Bank (MCB) and a Working Cell Bank (WCB) of [**] in accordance with ICH, EMA and FDA guidelines and with European and US pharmacopoeias (EP/USP)

2. Locations

The Work will be performed by NOVASEP in its facilities in Gosselies and Seneffe (Belgium). The production facilities will be operated by NOVASEP in compliance with current GMP rules with respect to the Clinical Batches and all applicable laws.

3. Project and technical team

<u>Name</u>	<u>Department</u>
[**]	Director, Strategic Projects
[**]	Research & Development
[**]	Production
[**]	Quality Control
[**]	Quality Assurance
[**]	Qualified Person
[**]	CMO Biopharma Market
[**]	Area Sales Manager

NOVASEP's representative [**] will be FREELINE THERAPEUTIC's main point of contact for all commercial as well as technical questions related to this Agreement until the project proposal agreed and purchase order (PO) received from CUSTOMER. Once a project is started, the allocated Project Manager will take over for all aspects related to the operational level.

4. Project Management

At NOVASEP, we have recognised over the years that successfully managed projects increase productivity, yield a greater return on investment, increase profits, and improve customer service.

Moreover, NOVASEP considers that communication between NOVASEP and each customer is key to align strategies, share and assess risks, manage changes, especially in the field of new products.

NOVASEP will assign a Project Manager to this project who will be the main contact for both internally and externally. To maintain a close working relationship, periodic project meetings will be scheduled. During these meetings, progress of the project will be reviewed and both Parties will make sure that they are aligned to a common set of goals.

5. Prerequisites

FREELINE THERAPEUTICS will provide a series of vials of [**] including requested documentation [**] allowing their introduction into NOVASEP's cGMP facility.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

6. Summary of the work

WP	Description	Approx. duration
WP 1.	Master & Working Cell Bank manufacturing and release	4-5 months

7. Detailed description of the work packages

1. Work package 1. Master Cell Bank & Working Cell Bank manufacturing and release

WP 1.1. Production of a Master Cell Bank (MCB)

A MCB will be produced in the GMP facilities starting from a vial of [**] to which FREELINE THERAPEUTICS has access.

The MCB will be produced in adherence (static mode) to allow the production of [**] containing [**] cell/ml \pm [**] with a viability [**]

The following in-house analytical testing will be performed on the MCB under the responsibility of NOVASEP.

Process testing	Method	Specification
Sterility	[**]	Absence of growth
Appearance	[**]	For example (Turbid, yellowish liquid)
Cell Viability	[**]	For example (³ 60% at thawing step)
Total cell count	[**]	For example (³ 1.5 10 ⁷ cells/vial)
Growth recovery	[**]	i.e. Cell doubling time \leq 50h; Viability ³ 80% at 2nd passage after thawing

The following outsourced QC will be done under the responsibility of the subcontractor (**). Additional outsourced QC testing would be performed upon FREELINE THERAPEUTICS request.

Process testing	Method	Specification
Cell identity DNA Fingerprint To include Large T antigen	To be defined	[**]
Mycoplasma: Direct & Indirect	To be defined	No evidence of Mycoplasma
Retrovirus detection	Co-cultivation assay with [**] 5 passages and F-PERT end point EP5.2.3	Absence of retrovirus
Karyotype	Optical and electron microscope	Diploid cells TBD
Morphological characteristics and growth characteristics	To be defined	No evidence of Mycobacteria
Mycobacteria	Preparation and examination of 200 median cell profiles by TEM	Absence of virus
Transmission electron microscopy	To be defined	No evidence of cytopathic effect or haemadsorption
In Vitro AA [**]	To be defined	No evidence of virus
In Vivo AA (adult mice, suckling mice, guinea pigs & embryonated eggs)	To be defined	No retrotranscriptase activity
Reverse transcriptase activity (F-PERT) Detection of Human Viral Pathogens	To be defined	No bovine viruses
Detection of bovine viruses (9 CFR)	To be defined	No porcine viruses
Detection of porcine viruses (9 CFR)*	To be defined	No porcine Circovirus 1 & 2
Detection of porcine Circovirus 1 & 2*	To be defined	Absence of Enterovirus
Detection of Enterovirus	To be defined	No evidence of virus
Detection of human viruses: [**]	qPCR	

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

* If porcine trypsin was used in the bank production performed by ATCC. ** If the sub-contractor of the assay requested by FREELINE THERAPEUTICS is not qualified yet by NOVASEP, an extra cost will be requested to FREELINE THERAPEUTICS in order to perform a documentary audit or on site audit of the sub-contractor.

Duration: approx 4 months, including release and production report.

Deliverables: approx [**] executed Batch Records, signed CoAs

WP 1.2. Production of a Working Cell Bank (WCB)

A WCB will be produced in the GMP facilities starting from [**] produced in WP1.1.

The process will allow the production of [**] and each vial will contain [**] with a viability [**] The process will be performed at the same scale as for the production scheme defined at step WP1.1.

The following in-house analytical testing will be performed on the WCB under the responsibility of NOVASEP.

<u>Process testing</u>	<u>Method</u>	<u>Specification</u>
Sterility	[**]	Absence of growth
Appearance	[**]	For example (Turbid, yellowish liquid)
Cell Viability	[**]	For example (³ 60% at thawing step)
Total cell count	[**]	For example (³ 15 10 ⁷ cells/vial)
Growth recovery	[**]	i.e. Cell doubling time £ 50h and viability ³ 80% at 2nd passage after thawing

The following outsourced QC will be done under the responsibility of the subcontractor (*). Additional outsourced QC testing would be performed upon FREELINE THERAPEUTICS request.

<u>Process testing</u>	<u>Method</u>	<u>Specification</u>
Cell identity DNA Fingerprint To include large T antigen	To be defined	[**]
Mycoplasma Direct & Indirect	To be defined	No evidence of Mycoplasma
In Vitro AA [**]	To be defined	No evidence of cytopathic effect or haemadsorption

* If the sub-contractor of the assay requested by FREELINE THERAPEUTICS is not qualified yet by NOVASEP, an extra cost will be requested to FREELINE THERAPEUTICS in order to perform a documentary audit or on site audit of the sub-contractor.

Duration: approx 4 months, including release and production report.

Deliverables: approx approx, [**] executed Batch Records, signed CoAs

Part 3: Price of the Work and Payment conditions

1. Price

The price for the Work (in EURO) described above is as follows:

<u>WP</u>	<u>Description</u>	<u>Price</u>
WP 1.	Master & Working Cell Bank manufacturing and release	[**]
External Costs		[**]
		TOTAL BUDGET: [**]

External Costs

Raw materials, consumables, disposables and reagents linked to the process (e.g. culture media, chromatographic resins, membranes, filters, ...) and outsourced QC testing are defined as external costs and are included in the above budget. External costs have been firstly estimated at [**]

In case these costs exceed the said amount, NOVASEP will invoice FREELINE THERAPEUTICS for these additional costs with [**] overhead.

Should the External Costs amount effectively borne by NOVASEP at the expiration/termination date of this Agreement be less than the above mentioned estimated External Costs, the Parties hereby agree that the difference shall be credited to FREELINE THERAPEUTICS.

Transport/shipment is not included in the present offer and will be re-invoiced with [**]

The [**] only includes NVS administration fees related to outsourcing management (accounting, organization & contract with subcontractors).

Costs of storage or destruction of any product, intermediate or unused raw material are not included in the prices specified in this Part 3 Such costs, if any, will therefore be charged by NOVASEP to FREELINE THERAPEUTICS in addition to these prices. Any exceeding storage of raw materials or Products in relation with a change of initial agreed delivery date of postponement or cancellation of any Work Package by FREELINE THERAPEUTICS will be charged by NOVASEP to FREELINE THERAPEUTICS in addition to the prices defined in this Part 3.

2. Validity

The offer included in this Agreement is valid thirty (30) days after date of receipt.

3. Applicable Incoterm

The deliveries are quoted FCA NOVASEP Facility in Belgium (Incoterm 2010 of the ICC), the transport and insurance stay at the customer cost

Should NOVASEP provide assistance to CUSTOMER for the organization of the shipment of the Product / Deliverables and/or choose the shipping agents and companies on behalf of CUSTOMER, the transfer of risks for those Product / Deliverables from NOVASEP to CUSTOMER shall anyway occur in accordance with the agreed Incoterm 2010 of the ICC, i.e. NOVASEP will NOT be responsible or liable for the damages or loss that could occur on the Product / Deliverables during transportation.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

4. Payment Conditions

CUSTOMER agrees to make payments of the price set out in Section 1 of this Part 3 [**] against invoices, as set out in Section 5 of Part 3, upon the following installments:

#	Payment terms	%
1	Upon signature of the Agreement	[**]
2	Upon release of MCB	[**]
3	At starting the preparation of the WCB manufacturing	[**]
4	Upon release of the WCB	[**]

5. Payment terms

First payment (at signature): upon invoice reception, () by bank transfer, non-refundable.

Other payments: 30 days net date of invoice (), by bank transfer.

In case of late payments, NOVASEP will be entitled to invoice a penalty up to [**] the global price per week of delay to CUSTOMER.

6. NOVASEP's Bank Account

HENOGEN S.A
rue des Professeurs Jeener et Brachet 12
6041 Gosselies
Belgium
TVA: [**]
Bank name: [**]
IBAN: [**]
BIC/SWIFT: [**]

1 Integral Parts of this Agreement

The present Agreement contains 4 parts, which are an integral part thereof:

- Part 1: Definition
- Part 2: Scope of the Work;
- Part 3: Price of the Work and Payment Conditions
- Part 4: Legal Terms

2 Work

2.1 **Scope of Work.** CUSTOMER hereby engages NOVASEP to conduct the Work and NOVASEP hereby agrees to provide the Work for CUSTOMER in accordance with this Agreement, at the rates or for all sums set out in Part 3 and otherwise upon these terms and conditions. Any services not expressly described as being included in the Work as set forth in Part 2 will be considered to be outside NOVASEP's scope of Work and will be charged to CUSTOMER at NOVASEP's then applicable rates, provided that Novasep has notified CUSTOMER that such services are outside NOVASEP's scope of Work and CUSTOMER has given its prior written consent to Novasep carrying out such services.

2.2 **Change of scope.** Any change of scope by CUSTOMER shall be subject to a written agreement of both Parties, such agreement including revised timelines, prices, specifications, quality and/or HSE requirements. Should CUSTOMER ask for a change in the agreed packaging of the Product, or in the agreed batch size(s), or in the agreed size of vials NOVASEP will notify CUSTOMER of any costs or expenses resulting therefrom, including additional manufacturing, handling, sampling, packaging or storage costs or expenses and if CUSTOMER requests NOVASEP to proceed with such change, such costs and expenses will be borne by CUSTOMER.

2.3 **Storage and destruction costs.** Cost of destruction of any product, intermediate or unused raw material are not included in the prices specified in Part 3 Such costs, if any, will therefore be charged by NOVASEP to CUSTOMER in addition to these prices. Any exceeding storage of raw materials or Products in relation with a change of initial agreed delivery date of postponement or cancellation of services by CUSTOMER will be charged by NOVASEP to CUSTOMER.

2.4 **Equipment.** Should NOVASEP purchase specific equipment, softwares, systems and devices in connection with the performance of the Work, such items shall, unless otherwise expressly agreed between the Parties, be owned by NOVASEP.

2.5 **Use of CUSTOMER Data and Materials.** CUSTOMER hereby authorizes NOVASEP and its employees to use the customer Data and the Materials to the extent necessary to perform the Work. NOVASEP acknowledges and recognizes that no other right or license to use in any way the customer Data or the Materials is granted hereunder, by implication or otherwise.

2.6 The Parties shall collaborate in good faith and in transparency for the proper performance of the Work.

3 NOVASEP's undertakings

3.1 NOVASEP warrants and undertakes to CUSTOMER (i) that the Work will be conducted in a professional manner with professional skill and care and (ii) that NOVASEP will use its good faith efforts to perform the Work in accordance with the indicative time schedules set out in the Part 2 and in accordance with the terms of this Agreement. It is acknowledged between the Parties that since the Work is of developmental nature, there can be no guarantee that the Work will be successfully completed, or that the Product and/or the deliverables will be in full conformity with the Product's specifications, or that the Work will be completed within a specified time frame, despite NOVASEP's good faith efforts to do so. In the event that the Product fails to meet specifications due to operator error, equipment/building failure or other issue in Novasep's control then Novasep will repeat the work at its cost to deliver the Product with reasonable efforts to minimize delay.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

3.2 Except as expressly otherwise stated in this Agreement, NOVASEP expressly excludes and disclaims all other warranties (whether implied or express), including, without limitation: (i) any warranty of merchantability or (ii) any warranty of fitness of the Products and deliverables supplied under this Agreement for the particular purpose for which CUSTOMER intends to use them.

3.3 **Audit.** Maximum once a year, CUSTOMER may conduct on site compliance quality audits of NOVASEP to inspect areas, equipment and materials of the facility where the Work is performed, including procedures and data connected with the Work. NOVASEP shall receive prior reasonable notice of such audit at least thirty (30) business days in advance, in order to make relevant staff available to attend the audit. Such audit shall take place during normal business hours. CUSTOMER shall use its reasonable endeavors not to cause any disruption to NOVASEP's business and activity in carrying out such audit. In the event the audit under this Section extends beyond two business days, NOVASEP will charge CUSTOMER a per diem rate of [**] which shall include reasonable access to NOVASEP's qualified and experienced employees. For the avoidance of doubt, such right of CUSTOMER does not include any right to inspect or audit NOVASEP's financial data or accounting records.

3.4 **Other Services.** If NOVASEP, at CUSTOMER's request, provides assistance or services to CUSTOMER for the importation of any raw materials, intermediates or substances, or for the exportation of the Product or any deliverable, such services will be invoiced by NOVASEP to CUSTOMER at a [**]

4 CUSTOMER's obligations and Supplies

4.1 **General obligation of CUSTOMER.** As a general obligation, CUSTOMER shall perform the tasks assigned to it as defined in this agreement. CUSTOMER shall also supply NOVASEP sufficiently in advance with such materials, information and documents as NOVASEP may reasonably request for the proper performance of its obligations hereunder, as more specifically described in Part 2. CUSTOMER shall also take delivery of the Product manufactured by NOVASEP at NOVASEP's facility within seven days following NOVASEP's notice of readiness to the customer.

4.2 **Supply of Materials by CUSTOMER.** If CUSTOMER has to supply Materials to NOVASEP according to this agreement, in particular Part 2 or any other arrangement, then it is the responsibility of CUSTOMER to ensure that adequate quantities of such Materials are delivered on time and with appropriate quality to NOVASEP's facility. Should the late arrival of such Materials, or the quality of such Materials, negatively impact the performance of the Work or the indicative time schedule defined in Part 2, then NOVASEP shall not be liable for the consequences of such late delivery and CUSTOMER shall compensate NOVASEP for any additional costs of laboratory services and facilities downtime provided that such facilities could not be reasonably reallocated by NOVASEP.

4.3 CUSTOMER's Warranties.

a) CUSTOMER hereby warrants and undertakes that any CUSTOMER Data, Materials and Product which NOVASEP is required by CUSTOMER to use, access or modify is legally licensed to CUSTOMER or is CUSTOMER's own property, and that as far as CUSTOMER is aware as at the date of signing of this Agreement, NOVASEP's Work activities under this Agreement will not infringe the rights of any third parties.

b) CUSTOMER also warrants and represents to NOVASEP that the nature of the Materials and Product delivered by or on behalf of the customer to NOVASEP will conform to all relevant legal requirements.

c) In addition, CUSTOMER warrants and represents to NOVASEP that the nature of the Materials and Product delivered by or on behalf of the customer to NOVASEP will be free of hazardous or toxic material unless clearly specified for known hazardous materials such as cytostatic/cytotoxic materials. Material Safety Data Sheets and any specific safe material handling instructions applicable to the Materials and Product will be disclosed by CUSTOMER in advance to NOVASEP in writing and included with shipments. Before the beginning of the Work, CUSTOMER shall supply NOVASEP free of charge with copies of all safety information relating to the Materials and Product.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

5 Intellectual Property Rights

5.1 The following definitions shall apply to this Agreement:

“**Intellectual Property Rights**” means copyright, design right, database rights, trade marks (whether registered or unregistered), patents, patent applications, registered designs rights and all other rights of a similar nature, subsisting anywhere in the world at any time.

“**NOVASEP Background Intellectual Property**” means all inventions, information, processes, software, know-how, data, discoveries, reports, materials, techniques or methods, including Intellectual Property Rights, which are in possession of NOVASEP prior to the date of the signing of this Agreement, or which is developed by NOVASEP in parallel with this Agreement without using any CUSTOMER Data in connection with this Agreement.

“**CUSTOMER Background Intellectual Property**” means all inventions, information, processes, software, know-how, data, discoveries, reports, materials, techniques or methods, including Intellectual Property Rights, which are in possession of CUSTOMER prior to the date of the signing of this Agreement, or which is developed by CUSTOMER in parallel with this Agreement without using any Confidential Information of NOVASEP in connection with this Agreement.

“**Results**” means any data, methods, substances and/or materials produced, developed by NOVASEP in the course of and relating to the Work (whether individually, collectively or jointly with CUSTOMER), including, without limitation, NOVASEP’s development reports.

5.2 NOVASEP Background Intellectual Property shall at all times remain the sole and exclusive property of NOVASEP.

CUSTOMER Background Intellectual Property shall at all times remain the sole and exclusive property of CUSTOMER.

Each Party hereby grants the other Party a worldwide, royalty-free, non-exclusive license, without the right to sublicense, to use its Background Intellectual Property as necessary for the purpose of carrying out the Work, but for no other purpose.

5.3 Subject to Section 5.4 below, all right, title and interest in and to the Results which are specific to the customer’s Product, are the sole property of CUSTOMER, and all such rights shall pass to CUSTOMER upon receipt by NOVASEP of the full payment of the Work by CUSTOMER.

NOVASEP shall, at CUSTOMER’s request and at CUSTOMER’s costs, perform all such activities and sign all documents deemed necessary by CUSTOMER to enable CUSTOMER to obtain the rights described in this section 5.3.

5.4 All right, title and interest in and to the Results which are not specific to the customer’s Product are the sole property of NOVASEP and all such rights shall pass to NOVASEP as soon as they are created.

CUSTOMER shall, at NOVASEP’s request and at NOVASEP’s costs, perform all such activities and sign all documents deemed necessary by NOVASEP to enable NOVASEP to obtain the rights described in this Section 5.4.

5.5 The Party who is the sole owner of a Result is free to use its Result and may take such steps as it may decide from time to time, at its expense and sole discretion, to register and maintain any protection for that Result including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of its Intellectual Property Rights. Where any third party is involved in the Work, the Party engaging that third party will ensure that the third party assigns to it any Intellectual Property they may have in the Results in order to be able to give effect to the provisions of this Section 5.

5.6 Notwithstanding the foregoing, no patent application shall be filed by either Party regarding the Results without the prior written information thereof of the other Party, including the patent draft or a translation thereof in French or English, at least four weeks prior to the contemplated patent filing date. The Party desiring to patent shall not unreasonably refuse or omit to take into account any comments received from the other Party.

5.6 Each Party grants the other Party a worldwide, royalty free, fully paid up, non-exclusive license, without the right to sub-license, to use its Results for the purpose of carrying out the Work.

5.7 In case Product samples and/or batches are delivered by NOVASEP to CUSTOMER within the scope of this Agreement, such Product samples and/or Product batches shall belong to the customer, which shall be free to use them.

7 Confidentiality

7.1 The Receiving Party shall keep strictly confidential all Confidential Information of the Disclosing Party and shall not disclose the same to a third party without prior written consent of the Disclosing Party.

7.2 The foregoing obligations of confidentiality shall not apply to any portion of the Confidential Information of the Disclosing party that the Receiving Party can demonstrate by contemporaneous documentary evidence:

- (a) was fully in its possession prior to receipt from the Disclosing Party; or
- (b) was in the public domain at the time of receipt from the Disclosing Party; or
- (c) became part of the public domain after the time of receipt from the Disclosing Party through no fault of the Receiving Party, or
- (d) was lawfully received by the Receiving Party from a third party having a right of further disclosure and who did not, directly or indirectly, receive such Confidential Information from the Disclosing Party; or
- (e) is required by law, regulation, rule, act, or order of any governmental authority or agency to be disclosed by the Receiving Party, provided, however, that the Receiving Party gives the Disclosing Party sufficient advance written notice to permit the Disclosing Party to seek a protective order or other similar order with respect to such Confidential Information and thereafter discloses only the minimum Confidential Information required to be disclosed in order to comply.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Information is embraced by general disclosures in the public domain or in the possession of the Receiving Party. In addition, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements thereof are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

7.3 Confidential Information shall not be used by the Receiving Party other than for the purpose of the work contemplated by this Agreement. The Parties shall only disclose Confidential Information to employees who have a genuine need to access such information in order to fulfil the Parties' obligations under this Agreement.

7.4 The Receiving Party agrees that, at the other Party's request, or upon expiration or termination of this Agreement (whatever the reason), the Receiving Party shall forthwith return to the other Party any and all parts of the Confidential Information of the Disclosing Party provided in documentary form and will return or destroy any copies or other tangible embodiments thereof made by the Receiving Party: except for one copy that may be retained in a secure file for compliance purposes only.

7.5 For the purposes of this clause 6 but subject to section 5, the Results shall be treated as Confidential Information.

7.6 Neither Party shall, without the prior written consent of the other Party, disclose to any third party the terms of this Agreement, which shall be treated as Confidential Information.

7.7 These obligations of confidentiality and non-use are valid during the period of this Agreement and for a period of [**] years after its termination. Each party agrees to indemnify the other from any loss suffered as a result of the violation of the provisions in this clause 7. The Receiving Party shall be liable for any acts or omissions of any person to whom it has disclosed the Confidential Information of the Disclosing Party, which, if effected by a Party to this Agreement, would constitute a breach of this Agreement.

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

8 Fees and expenses

8.1 CUSTOMER shall pay NOVASEP all sums as specified in Part 3. Unless otherwise agreed, all prices of NOVASEP are lump sum amounts. Such prices are for delivery of FCA NOVASEP's plant (Incoterms 2010 of the ICC). Payment on signature of this Agreement made by CUSTOMER in accordance with Part 3 will be considered non-refundable.

8.2 Unless otherwise agreed between the Parties, CUSTOMER shall pay all applicable taxes, duties and charges, if any, including taxes, duties and charges for transportation, insurance, shipping, storage and custom clearance of the Product and the deliverables. CUSTOMER shall obtain at its own expense any export and import license or other official authorization and carry out all customs formalities necessary for the exportation and/or importation of the deliverables.

8.3 NOVASEP shall issue invoices to CUSTOMER in respect of its fees, charges and expenses in accordance with the payment terms defined in Part 3.

8.4 The performance of the Work by NOVASEP may be subject to change in laws and regulations, in particular (but not only) as a result of the application of the European REACH regulation (1907/2006). For any change in legislation which results in additional costs for Novasep, these costs will be borne by CUSTOMER, after prior notice by NOVASEP informing CUSTOMER about the change in regulation and the additional costs resulting therefrom and after obtaining CUSTOMER's written agreement.

9 Term and Termination

9.1 This Agreement shall commence on the Effective Date, and shall continue (subject to earlier termination in accordance with this Agreement) in accordance with the indicative time frame set forth in Part 2, and expire when the Work is completed, unless otherwise agreed between the Parties.

9.2 Either Party may terminate this Agreement if the other is in material breach of this Agreement provided that such breach (where capable of remedy) has not been remedied within sixty (60) days of receipt of written notice from the terminating Party specifying the breach.

9.3 In addition to this, CUSTOMER may terminate this Agreement for convenience with a prior written notice of [**]

10 Effect of Termination

10.1 On the termination or expiration of this Agreement, CUSTOMER shall in accordance with this Agreement pay NOVASEP for all unpaid fees and expenses accrued up to the date of termination or expiration, and NOVASEP shall notwithstanding return all CUSTOMER Data to CUSTOMER forthwith, including any quantity of Product already manufactured by NOVASEP.

10.2 On the termination of this Agreement due to material breach from a Party, the other Party is entitled to compensation or reimbursement of fees and expenses paid under this Agreement NOVASEP shall upon termination of this Agreement (whatever the reason) return all CUSTOMER Data to CUSTOMER forthwith, save for one copy which may be retained by NOVASEP for the sole purpose of monitoring its confidentiality undertaking as defined in this Agreement.

10.3 If the Agreement has been terminated by CUSTOMER for convenience in accordance with Section 9.3 above, CUSTOMER shall pay to NOVASEP for [**] CUSTOMER shall pay to NOVASEP a termination fee corresponding to [**] due for all the work described Part 2 of the Agreement For the avoidance of doubt, the total amounts to be paid by CUSTOMER to NOVASEP under this Section 9.3 shall not exceed [**]

11 Liability

11.1 Each Party shall indemnify the other and hold the other harmless from and against any and all (i) liability for death, illness or injury to any third party; (ii) for loss or damage to any third party's property; and (iii) against all claims, demands, proceedings and causes of action resulting directly or indirectly therefrom, arising out of each Party's activities, negligence or wrongful act in the performance of the Work. Where a Party (the "Indemnitee") seeks indemnification from the other Party (the "Indemnitor") under this Agreement, the Indemnitee shall provide prompt written notice to the Indemnitor of the assertion or commencement of the relevant claim. The Indemnitor shall have the right to assume the defense of any such claim and shall not be liable for settlement of any claim effected without its written consent. The Indemnitee shall: (a) provide all assistance and information reasonably required by the Indemnitor; (b) not make any admission of liability, conclude any agreement in relation to such liability or make any compromise with any person, body or authority in relation to such liability without the prior written consent of the Indemnitor; and (c) have the right to participate in (but not control) the defense of a claim and to retain their own counsel in connection with such claim at their own expense.

11.2 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOSSES OF PROFITS), WHETHER IN CONTRACT OR IN TORT, ARISING OUT OF ANY TERMS OR CONDITIONS IN THIS AGREEMENT OR WITH RESPECT TO THE PERFORMANCE THEREOF, EXCEPT IN CASE OF GROSS NEGLIGENCE OR WILFUL MISCONDUCT.

11.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, THE LIABILITY OF NOVASEP ARISING OUT OF ANY TERMS OR CONDITIONS IN THIS AGREEMENT OR WITH RESPECT TO THE PERFORMANCE THEREOF SHALL BE IN ANY CASE LIMITED TO [**]

11.4 Notwithstanding any other provision of this agreement, neither party's liability under or in connection with this agreement shall be excluded or reduced to the extent that it arises in respect of the following matters:

- (a) for death or personal injury;
- (b) for fraud or fraudulent misrepresentation;
- (c) for breach of Section 7 (Confidentiality).

12 Applicable Law - Litigations

12.1 This Agreement shall be entirely and exclusively interpreted and enforced in accordance with the laws of Belgium.

12.2 In case of disputes between the Parties arising from the enforcement and/or the interpretation of the Agreement, the Parties shall try to settle amicably and rapidly such dispute. It is expressly agreed between the Parties that if no settlement can be found between them within a reasonable period of time, and in any case no later than two (2) months following the receipt by one Party of the written claim of the other Party, any disputes shall be brought in the Courts of Brussels, Belgium, which shall have exclusive jurisdiction.

13 Force Majeure

13.1 In this Agreement, Force Majeure means in relation to either Party, any circumstances beyond the reasonable control of that Party, preventing or delaying the performance by such Party of its obligations under this Agreement;

13.2 The following events are notably (but not exclusively) considered as events of Force Majeure: war (whether or not declared), revolutions, riot or civil commotion, accident, fire, explosions, flood, storm, delay in transportation, equipment breakdowns, change of laws or regulations, orders or acts of any governmental agency or body, labour conflict or strikes, shortage or disruption in supplies of raw materials.

13.3 If any Force Majeure occurs in relation to either Party which affects or may affect the performance of any of its obligations under this Agreement, it shall notify the other Party forthwith as to the nature and extent of the circumstances in question.

13.4 Neither Party shall be deemed to be in breach of this Agreement, or shall be otherwise liable to the other Party, by reason only of any delay in performance, or the non-performance of any of its obligations hereunder, to the extent that the delay or non-performance is due to any Force Majeure of which it has duly notified the other Party, and the time for performance of that obligation shall be extended accordingly.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

13.5 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for a continuous period in excess of ten (10) working days, the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

13.6 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for ninety (90) days or more, consecutively or cumulatively, in any one year, then the other Party shall in its discretion have the right to terminate this Agreement forthwith upon written notice.

14 General

14.1 This Agreement is binding upon and for the benefit of the undersigned Parties, their successors and assigns. The Parties are not entitled to assign or sub-contract any of their obligations under this Agreement without the other Party's prior written consent, except in case of subcontracting, transfer or assignment to one of their Affiliates.

14.2 Each Party is an independent contractor and neither is the agent of the other.

14.3 If any provisions of this Agreement shall be held by a court of competent jurisdiction to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect. In such event, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision within the limits of applicable law or applicable court decisions.

14.4 It is understood and agreed between the Parties that no failure or delay by a Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

14.5 This Agreement, along with its appendices, if any, constitute the entire agreement between the Parties with respect to the subject matter hereof, and it is expressly agreed that any and all prior understandings or agreements between the Parties relating to the subject matter of this Agreement, whether oral or written, are automatically cancelled by the execution of this Agreement.

14.6 The terms and conditions set forth in the Agreement and its appendices may only be modified in a subsequent writing signed by the Parties.

14.7 All notices to be given under the Agreement shall be in writing in English and left at or sent by first class registered or recorded delivery mail, or fax to the appropriate address shown in clause 14.8 or left at or sent to such other address as the Party concerned may from time to time designate by notice pursuant hereto.

14.8 The Parties contact information is:

For NOVASEP:

[**]
[**]
CEO
Email: [**]
Tel: [**]

For CUSTOMER:

[**]
[**]
CEO
Email: [**]
Tel: [**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Made in two original copies, one for each Party.

Signed by a duly authorized signatory for and on behalf of **HENOGEN SA**

Signed by a duly authorized signatory for and on behalf of **FREELINE THERAPEUTICS**

Signature: [**] _____
Name: [**]
Position: Chief Executive Officer
Date: 13/06/2016

Signature: [**] _____
Name: [**]
Position: CEO
Date: 6/6/16



Services Agreement

This services agreement, hereafter referred to as the “**Agreement**”, is entered into on 11th OCT. 2016 (the “**Effective Date**”) by and between

FREELINE THERAPEUTICS LIMITED, a company incorporated in England (Company No. 09500073) with registered office address at 215 Euston Road, London NW12BE, United Kingdom

hereafter referred to as “**FREELINE THERAPEUTICS**” or “**CUSTOMER**”,

and

HENOGEN SA (a subsidiary of the NOVASEP group), a Belgian corporation having its registered address at 12 rue des Professeurs Jeener et Brachet, B-6041 Gosselies, BELGIUM,

hereafter referred as “**NOVASEP**”.

CUSTOMER and NOVASEP will be hereafter be referred to separately as a “**Party**” and jointly as the “**Parties**”.

WHEREAS:

- (i) FREELINE THERAPEUTICS wishes to engage NOVASEP to conduct Work on the development and production of clinical trial supplies of therapeutic products owned by FREELINE THERAPEUTICS using an rAAV vector (each, as applicable, a “Product”);
- (ii) NOVASEP provides contract manufacturing services including process development, process scale-up, validation, production, quality assurance, regulatory support, analytical development and quality control analysis to pharmaceutical and biotechnology companies including in cell culture, fermentation, synthesis, purification and fill & finish processes;
- (iii) NOVASEP has the professional skills and knowledge to, and is willing to, perform the Works detailed in each Work Plan on the terms and conditions set forth herein and in exchange for which the CUSTOMER agrees to pay NOVASEP the Price as set out in the relevant Work Plan in respect of the Work; and

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

(iv) The Parties are willing to explore (but without obligation or commitment of either Party) the feasibility of entering into a more substantial and long lasting agreement in relation with the Product(s) for the potential commercial production of the Product(s) including without limitation the Parties' respective investment in a facility for such potential future commercial production.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the adequacy of which is acknowledged by each of the Parties, the Parties hereto agree as follows:

Part 1: Definitions

In this Agreement, unless the context otherwise requires, the following expressions shall have the following meanings:

“Affiliates” means any company, corporation; firm, partnership or other entity which is directly or indirectly controlled by, or under the same control of any of the Parties, where control means the power, direct or indirect, to direct or cause the direction of the management and policies of such entity, whether by contract, through the by-laws of the aforementioned entities or otherwise;

“Agreement” means the present Agreement and all its Appendix(es) including all Work Plans and Quality Agreements agreed between the Parties during the Term and any amendments to any of the foregoing made in accordance with this Agreement;

“Batch” means the total quantity of Product obtained from one manufacturing run using the process at a specified scale, the purification of the Product, and the analytical activities as further described in the applicable Work Plan;

“Batch Records” means all of the documentation associated with the production and testing of a given Batch, including without limitation production records (including-the master production record). Raw Materials certificates of release, sampling documentation, out of specification and deviation reports, test results, investigative and corrective action reports. all applicable manufacturing process data (including any pertinent output from instrumentation), facility cGMP compliance verifications for the duration of the Batch’s production (including without limitation for Water For Injections (WFI) production system, Heating and Ventilation Air Conditioning (“HVAC”) system and clean room classification attainment at the time that the Batches are produced), the Certificate of Analysis, the Certificate of Compliance and any additional quality review and approval documentation, If applicable. To the extent such documentation has been disclosed by CUSTOMER to NOVASEP, or includes CUSTOMER Background Data, CUSTOMER Pre-Existing IPR, or constitutes CUSTOMER Foreground IPR, or has been developed specifically in relation to a Product, It shall be deemed to be CUSTOMER’s Confidential Information disclosed to NOVASEP pursuant to this Agreement. Otherwise such documentation (other than where It relates to Jointly Owned Foreground IPR) shall be deemed to be the Confidential information of the Party developing or generating the same. To the extent that such documentation relates to Jointly Owned Foreground IPR, it shall be deemed to be the Confidential Information of both Parties jointly In respect of which each Party shall be considered a Receiving Party and shall act in accordance with the confidentiality obligations on a Receiving Party as set out in this Agreement;

“Certificate of Analysis” means a certificate of analysis listing in relation to each Batch the tests performed by NOVASEP or a sub-contractor of NOVASEP (as permitted under this Agreement and agreed between the Parties), the Specification and the test results and confirming that the Product meets the Specification and such other criteria as identified on the certificate of analysis;

“cGMP” means current Good Manufacturing Practices as promulgated in ICH Q7A (Guideline on Good Manufacturing Practice for Active Pharmaceutical Ingredients) as relevant to each stage of Product development and/or manufacture; EU and US GMP requirements as defined In Eudralex Vol 4 and In EC Directives 2003/94/EC and 2005/28/EC, and in 21 CFR Parts 210, 211, 600 and 610 and Part 11 for activities directly related to final Drug Product manufacture and control as any of the foregoing may be amended from time to time; and anything which replaces or supersedes the same from time to time;

“cGMP Batch” means a Batch which is manufactured, or is stipulated in a Work Plan to be manufactured, according to cGMP;

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“cGMP Product” means a Product manufactured (or to be manufactured, as the context requires) under cGMP conditions;

“Competitor” means any pharmaceutical or biotechnology company with (i) an active Adeno-associated virus based programme of research or clinical development, or (ii) one or more products, whether in development or available on the market, which compete with those of CUSTOMER as may be the case from time to time during the Term;

“Confidential information” means any and all commercial and technical information, and whether patented or unpatented, including but not limited to documents, strategies, methods, procedures, know-how, trade secrets, pre-clinical and clinical test-data, or technical or marketing information regardless of method of storage, and copies thereof, disclosed by or on behalf of one Party (**“the Disclosing Party”**) to the other Party (**“the Receiving Party”**) pursuant to this Agreement. The Product and (save to the extent containing Confidential information of NOVASEP) Work Plans shall be deemed the Confidential information of CUSTOMER;

“Customer Background Data” means all data, CUSTOMER’s Confidential Information, methods, substances, samples and Materials provided to NOVASEP by or on behalf of CUSTOMER pursuant to this Agreement;

“Delivered”/“Delivery” has the meaning given in Section 3.3 of this Agreement;

“Drug Product” means the formulated Drug Substance in association with none, one or more other ingredients sterile filtered and aseptically filled into vials suitable for use as a medicinal product;

“Drug Substance” means the active component in solution in bulk form in a suitable container for frozen storage;

“Effective Date” means the date mentioned on top of the first page of this Agreement;

“Equipment” means those pieces of equipment described in a Work Plan and required or used by NOVASEP to produce the Product, including, without limitation, the related documentation regarding the design, validation, operation, calibration and maintenance of such equipment. Components of the Equipment shall also be deemed Equipment. **“Customer Equipment”** and **“Novasep Equipment”** shall be as defined in Section 2.4 of this Agreement;

“Facility” shall mean NOVASEP’s development and manufacturing facility(ies) where the Work will be carried out, as agreed between the Parties and set out in the relevant Work Plan;

“Field” means any and all uses of Adeno-associated virus constructs;

“Force Majeure” has the meaning given in Section 14 of this Agreement;

“Foreground IPR” means the Novasep Foreground IPR, the CUSTOMER Foreground IPR and/or the Jointly Owned Foreground IPR as the case may be;

“Good Industry Practice” means the degree of skill, care prudence, knowledge and foresight which would reasonably and ordinarily be expected of a skilled, professional, competent and experienced contract manufacturing organisation engaged in the development of manufacturing processes for, and the cGMP manufacture of products at a similar or equivalent stage of development or approval to the Product;

[**]

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“Intellectual Property Rights” means all Intellectual property rights, including (without limitation) patents, rights in patents, supplementary protection certificates, petty patents, utility models, trade marks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know how, techniques, rights in Confidential Information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the World, in each case for their full term and together with any renewals or extensions;

“Master Production Record” means the document, proposed by NOVASEP and subsequently approved in writing by CUSTOMER and which specifies the Raw Materials with their quantities and the packaging materials, together with a detailed description of the procedures and precautions required to produce a specified quantity of an intermediate, bulk or finished product as well as the processing instructions, including the in-process controls;

“Materials” means materials, Raw Materials, compounds or Intermediates supplied by or on behalf of CUSTOMER to NOVASEP or its Affiliates under Section 2.7 of this Agreement or procured by NOVASEP in accordance with Section 2.6 of this Agreement;

“Permitted Sub-contractor” has the meaning given in Section 2.1 of this Agreement;

“Price” has the meaning given in Section 2.1 of this Agreement;

“Product” has the meaning given in Recital (i) to this Agreement;

“Production Records” has the meaning given in Section 2.4 of this Agreement;

“Project Team” means the team established by the Parties per Work Plan, in advance of commencement of the Work, and detailed in a Work Plan, responsible for (without limitation) the management of the Work on a day-to-day basis and which will consist of include one project manager from each of NOVASEP and CUSTOMER to act as the primary day-to-day point of contact for the Parties in respect of a Work Plan (each a “Project Manager”);

“Quality Agreement” means the agreement between the Parties, to be entered into on or within thirty (30) calendar days of the Effective Date, defining (without limitation) the quality and cGMP responsibilities regarding the performance of the Work and quality aspects of the manufacture of the Product, and **“Quality Agreements”** will include any further quality agreements to be entered into between the Parties in respect of any other Work Plan; in the format of the template quality agreement at Part 4 of this Agreement;

“Raw Materials” media, resins, catalysts, raw materials, solvents, filters, membranes, disposable analytical test kits, disposable bags, and other items consumed during or for the performance of the Work;

“Reasonable Endeavours” shall mean using all reasonable care and skill and resources but having regard to the fact that the Work, including without limitation the method of manufacture of the Product, is experimental in nature and NOVASEP cannot be considered liable for issues (including without limitation those causing delays) arising for causes which could not reasonably have been known to NOVASEP at the relevant time;

“Regulatory Filings” means any or all applications, submitted to regulatory authorities for the purpose of seeking and obtaining marketing approval for the Product, and/or of the method of production of the Product as required by statute and any amendments or supplements thereto, and any other filings required by the regulatory authorities relating to the manufacture, testing, sale or distribution of any Product, including, without limitation, an NDA or BLA;

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“Results” means any and all data, methods, procedures, processes, substances and materials arising from Work undertaken by NOVASEP or its Affiliates (or any Permitted Sub-contractor) and pursuant to a Work Plan, and any and all documentation thereof. Results which relate to the upstream process, including cell culture, transfection, viral vector release and viral vector harvest shall be defined as **“Upstream Results”** and Results which relate to the downstream process, including clarification, chromatography, membrane filtration, formulation and fill & finish steps shall be defined as **“Downstream Results”**:

“Specification” means the specification of the Product (in Drug Product or Drug Substance form as applicable) as defined in the relevant Work Plan or as otherwise agreed in writing between the Parties;

“Steering Group” means the three (3) senior representatives of each Party identified in Part 5 responsible for (without limitation) overseeing the relationship between the parties under this Agreement, the progress of the Work and for attempting to resolve any disputes not resolved by the Project Team(s);

“Work” means the work and services to be conducted by NOVASEP or its Affiliates (or any Permitted Sub-contractor) pursuant to this Agreement and as more particularly described in all of the Work Plans;

“Work Package” means a work package as set out in the Work Plan.

“Work Plan” means, in respect of each of the Work to be provided to CUSTOMER, a document signed by the Parties in advance of commencement of the Work and which sets out, without limitation, the Specification, each Party’s activities, roles and responsibilities, the timeline for performance of the Work and completion of the Work, key decision points, training, budget, payment terms and the Project Team; and any amendments to a Work Plan agreed between the Parties during the conduct of the relevant Work (such as, without Limitation, to confirm the Specification once known) will be deemed part of that Work Plan. To the extent that the Parties agree that any timelines or Specifications are to be binding, these will be identified as such by mutual consent of the Parties in the Work Plan. For the avoidance of doubt, all other timelines and the Specifications will be deemed to be indicative and non-binding;

“Work Plan IP” means any intellectual Property Rights generated, acquired or otherwise arising from or as a result of the Work carried out pursuant to the applicable Work Plan;

“Written” or **“in writing”** means either paper hardcopy or facsimile signed by both Parties or mail confirmed by both Parties.

1 Integral Parts of this Agreement

The present Agreement contains the following parts, each of which is an integral part thereof;

- Part 1: Definitions
- Part 2: Legal Terms
- Part 3: Work' Plans (to include Price and any variation to pricing terms)
- Part 4: Quality Agreements
- Part 5: The Steering Group
- Part 6: Customer Pre-Existing IPR
- Part 7: NOVASEP Pre-Existing IPR
- Part 8: Cancellation Fees

2 Work

2.1 **Scope of Work.** NOVASEP will conduct the Work (i) in accordance with the relevant Work Plan(s), (ii) having regard to the timeline set out in that Work Plan, (iii) at the rates or for all sums set out in the relevant Work Plan, inclusive of any subcontracted analytical testing performed by any third party instructed by NOVASEP to carry out tests on the Product pursuant to the performance of the Work (the "Price") (subject to any withholdings or deductions as otherwise provided for in this Agreement); (iv) using Reasonable Endeavors and in accordance with Good Industry Practice, and (v) otherwise upon the terms of this Agreement, Any work or services not expressly described as being included in the Work as set forth in a Work Plan (as may be amended from time to time by the Parties) will be considered to be outside NOVASEP's scope of Work and will be charged to CUSTOMER at NOVASEP's then applicable rates provided that such services and charges have been pre-approved by CUSTOMER in writing prior to such services being undertaken and additional charges being incurred, CUSTOMER will not be liable for any charges which are not the subject of a Work Plan or that it has not pre-approved in writing prior to such charges being incurred. All Product to be manufactured for CUSTOMER pursuant to a Work Plan will be manufactured solely by NOVASEP at the Facility unless CUSTOMER agrees, by prior written consent (not to be unreasonably withheld, delayed or conditioned), that NOVASEP may subcontract certain of its obligations under a Work Plan to a third party (a "**Permitted Sub-contractor**"), or that some or all of the Work may take place at a different NOVASEP facility Where NOVASEP sub contracts any part of the Work to be performed by an Affiliate or a Permitted Sub-contractor, NOVASEP shall continue to be responsible to CUSTOMER for the performance (or non-performance) of such Work and the acts and omissions of such Affiliate or Permitted Sub-contractor.

2.2 **Change of scope.** Any change of scope of a Work Plan requested in writing by CUSTOMER or recommended in writing by NOVASEP (describing in reasonable detail the nature and reason for NOVASEP's recommended changes) and accepted by CUSTOMER (at CUSTOMER's sole election) shall be subject to a written agreement of both Parties which will constitute an amendment to the applicable Work Plan, such agreement including revised timelines, prices, specifications, quality and/or health and safety or environmental requirements. Any additional scope items must be promptly prospectively agreed by CUSTOMER prior to NOVASEP incurring any expenditure in respect of such additional scope items and if any change of scope will have a financial or other impact on the Work, NOVASEP will provide CUSTOMER with a written description of such impact in a proposed amendment to the relevant Work Plan. Should CUSTOMER ask for a change in the agreed packaging of the Product, or in the agreed batch size(s), or in the agreed size of vials, any costs or expenses resulting therefrom, including additional manufacturing, handling, sampling, packaging or storage costs or expenses will be borne by CUSTOMER subject to CUSTOMER's approval. Any charge increase which results from an agreed change of scope will be priced in advance by NOVASEP in a reasonable manner on a milestone or time and materials basis, for discussion and subsequent agreement between the Parties in advance of being incurred.

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2.3 Storage and destruction costs. NOVASEP shall store (on CUSTOMER's behalf) at the Facility any Product or Materials for a maximum period of twelve (12) months from the date such Products or Materials are ready for delivery and shall store the Results at the Facility for a period of at least ten (10) years after such Results have been generated. For the avoidance of doubt and without limitation, any Information regarding the Facility and/or which pertains to the manufacture, testing and quality of the Product (including Batch Records) ("**Production Records**") shall be stored at the Facility for a period of at least ten (10) years after such information has been generated or for any such longer period as may be required by applicable laws and regulatory requirements of the European Union and the United States. Any storage of Products, Materials, Results or Production Records beyond the periods described above, shall be arranged by CUSTOMER who shall promptly collect the same from the Facility at CUSTOMER's expense. NOVASEP shall notify CUSTOMER of the expiry of any relevant storage period at least six (6) months prior to such expiry date, in writing to provide CUSTOMER sufficient time in which to arrange collection and alternative storage of the Products, Materials and/or Results (as may be applicable). If at the end of the relevant storage period (or such longer time as may otherwise be agreed between the Parties), the Product, Materials, Results and Production Records have not been collected by CUSTOMER, NOVASEP shall notify CUSTOMER of the outstanding collection. NOVASEP shall be entitled to destroy such Product, Materials, Results and Production Records following the expiry of sixty (60) business days from the date of notification of outstanding collection to CUSTOMER. Cost of destruction of any Product, Material, Results and Production Records are not included in the Price specified in the relevant Work Plan. Such reasonable costs, if any, will therefore be charged by NOVASEP to CUSTOMER in addition to the Price.

2.4 Equipment. Should NOVASEP purchase Equipment ("**NOVASEP Equipment**") such NOVASEP Equipment shall be owned by NOVASEP and be purchased at NOVASEP's cost save where the Parties have agreed in writing and prior to the acquisition of such NOVASEP Equipment that such NOVASEP Equipment will be used exclusively on behalf of CUSTOMER and in respect of a Work Plan(s) in which case such NOVASEP Equipment will be purchased at CUSTOMER's cost. If the Equipment is to be used in part on behalf of CUSTOMER and in part on behalf of third parties the Parties will determine in the relevant Work Plan their respective contributions thereto. Any acquisition, installation, validation or any other reasonable costs of any NOVASEP Equipment to be borne by CUSTOMER shall be expressly agreed in writing between the Parties in advance of such acquisition. Installation and validation being undertaken by or on behalf of NOVASEP (where such acquisition, installation and validation is not already Included in the Price).

Any Equipment provided by CUSTOMER to NOVASEP ("**CUSTOMER Equipment**") shall be owned by CUSTOMER and used solely by NOVASEP for the performance of the Work (unless CUSTOMER, in its sole discretion, agrees to permit other uses of CUSTOMER Equipment by NOVASEP). CUSTOMER will reimburse NOVASEP for any costs authorized for the installation and validation of any CUSTOMER Equipment and for the acquisition, installation and validation of any Equipment purchased by NOVASEP (not already included in the Price) and agreed between the Parties. NOVASEP will be responsible for the appropriate operation and maintenance of all NOVASEP Equipment and CUSTOMER Equipment, NOVASEP will return CUSTOMER Equipment to CUSTOMER at CUSTOMER's reasonable cost EXW NOVASEP site (Incoterms 2010) when such CUSTOMER Equipment is no longer required in respect of any Work Plan as determined by the Project Team, or within twenty (20) business days following termination or expiry of this Agreement or the relevant Work Plan (whichever is the earlier). Running costs and maintenance of CUSTOMER Equipment are included in the Price. NOVASEP will not permit, allow, cause, enable or assist any third party to use any CUSTOMER Equipment or NOVASEP Equipment (where such exclusive use of NOVASEP Equipment is specifically agreed between the Parties in writing) purchased by NOVASEP in accordance with this section and identified as being for exclusive use without CUSTOMER's prior written consent.

2.5 Use of Customer Background Data and Materials. CUSTOMER hereby authorizes NOVASEP and its employees to use the Customer Background Data and the Materials to the extent necessary to perform the Work, NOVASEP acknowledges and recognizes that no other right of license to use in any way the Customer Background Data or the Materials is granted hereunder, by implication or otherwise.

2.6 Supply of Materials by NOVASEP. Unless agreed in a Work Plan, NOVASEP shall be responsible for the procurement of all commercially available Materials necessary for the manufacture of the Product including safety stock amounts where applicable and stipulated in a Work Plan ("**NOVASEP-sourced Materials**"). Unless specified to the contrary, the price of the Materials shall be included in the Price set out in the relevant Work Plan. Title to all NOVASEP-sourced Materials shall pass to CUSTOMER immediately upon NOVASEP's receipt of full cleared payment for such NOVASEP-sourced Materials from CUSTOMER. All NOVASEP-sourced Materials that are in NOVASEP's control and are to be used in the manufacture of the Product, as well as Product in NOVASEP's control, shall be stored in accordance with any storage guidelines agreed between the Parties and with due skill and care, it is the responsibility of NOVASEP to ensure that such NOVASEP-sourced Materials comply with any applicable specifications specified by CUSTOMER, that adequate quantities of such NOVASEP-sourced Materials are procured and received on time and with appropriate quality to the Facility. Should the late arrival of such NOVASEP-sourced Materials negatively impact the performance of the Work or the time

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schedule in that Work Plan, NOVASEP shall, where such delay was due to the negligence or willful default of NOVASEP, be liable (subject to Sections 12.3 and 12.4 of this Agreement) for loss to CUSTOMER which could not otherwise have been avoided by CUSTOMER following such late delivery of such NOVASEP-sourced Materials (at no additional cost to CUSTOMER), other than where such late delivery of the NOVASEP-sourced Materials was exclusively due to the negligence or willful default of a third party and beyond the control of NOVASEP. In which case, NOVASEP shall use all Reasonable Endeavours to ensure that performance of the Work is as close to the time schedule in the Work Plan as possible.

2.7 Supply of Information and Materials by CUSTOMER. Where CUSTOMER supplies Materials or Customer Background Data to NOVASEP pursuant to a Work Plan or otherwise under this Agreement (“CUSTOMER-sourced Materials”), then it is the responsibility of CUSTOMER to ensure that adequate quantities of such CUSTOMER-sourced Materials are delivered on time and with appropriate quality to the Facility. Should the late arrival of such CUSTOMER-sourced Materials, or the quality of such CUSTOMER-sourced Materials, negatively impact the performance of the Work at the time schedule in an applicable Work Plan, then NOVASEP shall not be liable for the consequences of such late delivery and CUSTOMER shall compensate NOVASEP for any reasonably incurred additional costs of laboratory services and Facility downtime which could not otherwise have been avoided by NOVASEP and/or save to the extent such costs were attributable to the gross negligence or willful default of NOVASEP.

2.8 Project, Manager and Project Team. The Parties shall collaborate in good faith and in transparency for the proper performance of the Work via the Steering Group, the Project Manager and the Project Team. The Project Team will meet frequently either by telephone conference or if necessary, by face-to-face meetings, every two (2) weeks unless agreed otherwise, and for the duration of the relevant Work to ensure (amongst other things) that the Work is progressing in line with the time frames, to the Specification and any other requirements stipulated in the relevant Work Plan, to discuss and resolve any issues arising from the progression of the Work and to manage the Work on a day-to-day basis. In addition to the Project Team, each Party will assign a Project Manager (to be named in the relevant Work Plan) who will be the primary day-to-day point of contact for each Party.

2.9 Steering Group. Each Party will assign individuals to constitute the Steering Group on or before the Effective Date, whose roles will be as set out in this Agreement. The Steering Group will be co-chaired by the Parties and responsible for (amongst other things and without limitation) overseeing the relationship between the Parties in respect of all Work Plans and under this Agreement more generally and reviewing and approving any element of a Work Plan or this Agreement which requires the joint agreement of both Parties. The Steering Group will meet quarterly (or at such other frequency to be agreed between the Parties) or at the reasonable request of either Party during the Term in order for the Steering Group to meet its objectives. CUSTOMER members of the Steering Group will be responsible for drafting the minutes of each meeting of the Steering Group (the “Minutes”) and will circulate a draft set of Minutes as soon as reasonably practicable following the relevant meeting for approval. NOVASEP will have five (5) business days in which to review and approve the Minutes (or revert to CUSTOMER with proposed amendments). Any Minutes not expressly approved by NOVASEP within this timeframe will be deemed approved by both Parties and not subject to further amendment.

2.10 Replacements and Meetings. In the event of removal or replacement of any member of the Steering Group or Project Team (the “Departing Member”), the Departing Member’s Party will notify the other Party as far in advance as possible of the removal or replacement of the Departing Member and such Party will provide a replacement member for the Steering Group or Project Team (as applicable) with an appropriate level of experience, knowledge and technical skill. Each Party shall be responsible for its own costs in attending and conducting meetings between any or all of the Steering Group, Project Manager and/or Project Team. The Parties’ intention is that all issues considered by the Steering Committee will be resolved unanimously but in the event that a unanimous agreement cannot be reached on any issue relating to a Work Plan, the provisions of Section 13.3 will apply.

2.11 Product Specification. Where the Work Plan requires the manufacture of the Product to meet a Specification, NOVASEP will use all Reasonable Endeavours to manufacture the Product to meet that Specification. The Parties will agree the Specifications as far as possible prior to signature by both Parties of the relevant Work Plan, and any Specifications agreed during the course of a Work Plan will be proposed by the Project Teams to (the Steering Group for approval. In the event that any amendments to the Specification are necessary, such amendments will be negotiated by the Project Team and approved by the Steering Group, in each case in good faith acting reasonably. Where agreement cannot be reached, the dispute resolution provisions of this Agreement will apply.

2.12 Manufacturing Capacity and Reservations. NOVASEP will, on agreement of, and in accordance with, a Work Plan, reserve slots in its cGMP manufacturing suite for those cGMP Batches to be manufactured under the relevant Work Plan according to the time frame in that Work Plan. Where the time frame is amended in accordance with section 2.13 of this Agreement (amongst other

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sections) and such amendment affects the existing manufacturing schedule for Batches, NOVASEP will use reasonable endeavours to update its manufacturing schedule and reserve new slots for those affected Batches which will be reserved as near in time to the existing vacated slots as NOVASEP's then current schedule will permit. CUSTOMER may delay or cancel any slot reservation at any time upon prior written notice to NOVASEP subject to the payment of the delay and cancellation payments set out in Section 2.13 or Part 9 as applicable, and NOVASEP shall accordingly modify the time frame by delaying performance of those applicable Works associated with such delayed or cancelled slot.

2.13 Rescheduling. The manufacture of cGMP Batches or activities requiring the use of a cGMP Facility: CUSTOMER may delay or request the reschedule of any slot reservation for the manufacture of any cGMP Product or cGMP Batch, or any activities which require the use of a cGMP Facility (the "**Rescheduled Activity**" and the "**Reschedule Notice**") at any time upon prior written notice to NOVASEP. Where a Reschedule Notice is provided to NOVASEP at least 3 calendar months prior to the agreed start date of the work which is to be the Rescheduled Activity, the delay or reschedule will be at no additional cost to CUSTOMER provided that CUSTOMER requests that the Rescheduled Activity is rescheduled within 12 calendar months from the date the relevant work was originally due to commence and that the Rescheduled Activity has not already been delayed or rescheduled pursuant to this Section 2.13. NOVASEP will use its Reasonable Endeavours to accommodate the change in schedule and to complete the Rescheduled Activity within the time frame requested by CUSTOMER. In the event that a Reschedule Notice is provided less than 3 months prior to the start date of the relevant work or has already been delayed or rescheduled pursuant to this Section 2.13, CUSTOMER will pay NOVASEP a rescheduling fee [**] in respect of the Rescheduled Activity (excluding the cost of Raw Materials as applicable) (the "**Rescheduling Fee**"), save that if NOVASEP, using its Reasonable Endeavours, is able to allocate the capacity which results from the Reschedule Notice for any other work (whether in respect of CUSTOMER or any third party), NOVASEP will immediately refund the Rescheduling Fee to CUSTOMER less NOVASEP'S reasonable out-of-pocket expenses.

2.14 Replacement Product: CUSTOMER may choose to reallocate a cGMP Batch reservation to an alternative Product, on not less than 6 months' written notice to NOVASEP prior to the start of that cGMP Batch manufacture. NOVASEP will use its best efforts to accommodate CUSTOMER'S request, at no extra cost to CUSTOMER save any reasonable transfer costs and product-specific fees to be mutually agreed in advance in writing (for example, but without limitation, Product-specific analytical methods).

2.15 Reporting. On a non-binding, indicative timeframe to be agreed between the Parties in a Work Plan (or otherwise on a reasonable frequency and unless specified as being binding and indicative in the relevant Work Plan), NOVASEP will keep CUSTOMER updated as to compliance with the time frame set out in a Work Plan via the Steering Committee and the Project Team. For each Work Plan, NOVASEP will prepare and provide to CUSTOMER a report detailing the Results of development work by NOVASEP based on a structure and covering certain content to be mutually agreed by the Parties prior to the initiation of any Work Plan and detailing progress with respect to any timeline, prior to delivery of any Product and the Results to CUSTOMER (the "**Developmental Report**"). CUSTOMER will review such Developmental Report in a reasonable timeframe prior to acceptance of the Product and/or the Results (and thus acceptance of the completion of the relevant Work Package). In the event that acceptance of a Developmental Report gives rise to a payment obligation on CUSTOMER, such payment will not be due or payable until such time as a final version of the Developmental Report has been accepted by CUSTOMER, such acceptance not to be unreasonably withheld or delayed. CUSTOMER shall provide NOVASEP with its comments on a draft version of a Developmental Report within fifteen (15) business days of receipt of such draft. NOVASEP shall provide CUSTOMER with a final version of a Developmental Report integrating, as the case may be, the reasonable comments of CUSTOMER within a further fifteen (15) business days. In the absence of comments from CUSTOMER within the fifteen (15) business day period the draft version of a Developmental Report shall be considered final and any associated payment obligation shall become due and payable. Separate from the Developmental Report, NOVASEP will, for the duration of a relevant Work Plan, make available to CUSTOMER, on request, all Results and any other data relating to such Work Plan as CUSTOMER may reasonably require to support CUSTOMER in making any decisions in respect of the said Work Plan and/or the Product which is the subject of such Work Plan and in respect of any of CUSTOMER'S Product and regulatory activities and obligations.

2.16 Performance standards. For the avoidance of doubt NOVASEP shall use all Reasonable Endeavours in accordance with Good Industry Practice in the performance of the Work.

2.17 cGMP and Quality. NOVASEP will, where required under applicable regulatory obligations, comply with any applicable cGMP criteria for, and in its performance of, each aspect of the Work and with the requirements and recommendations stipulated in the International Conference on Harmonization guidelines on quality. NOVASEP will maintain, retain and store (i) materials generated from a run of the Product method of production (as used as a standard or reference for analytical testing purposes) of all cGMP Product for such period as required by applicable regulatory obligations; and (ii) all records required to be maintained by the terms of this

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Agreement or any Work Plan and by applicable laws and/or regulatory obligations. After termination or expiry of this Agreement, NOVASEP will provide copies or samples (as the case may be) of all such materials and records to CUSTOMER upon CUSTOMER'S request and NOVASEP will not (subject to Section 2.3) dispose of the same without CUSTOMER's prior written consent.

2.18 Qualification and Validation of NOVASEP's Facility, Utilities and Equipment. NOVASEP will maintain cGMP qualification and validation of the facility, as well as all utilities and equipment (including Equipment) used in the manufacture of the Product at the Facility, and shall make relevant reports applicable thereto available to CUSTOMER by way of copies or for review at the Facility, in either case at CUSTOMER's written request. The relevant Work Plan will specify certain testing, storage, release, cGMP, regulatory and other quality assurance requirements relating to manufacture and shipment of Product by NOVASEP under this Agreement.

2.19 Regulatory Filings and Maintenance. CUSTOMER will maintain and be the sole owner of and have full rights and freedoms to use all Regulatory Filings and all governmental approvals obtained from any regulatory authority with respect to the Product or the process of manufacture of the Product. NOVASEP will provide such documents and information to support and assist CUSTOMER in filing, prosecuting and securing Regulatory Filings and in maintaining regulatory authority approvals for the Product, as requested or as necessary in addition, NOVASEP will prepare and maintain and provide CUSTOMER with copies of manufacturing files, certificates, authorizations, data and other records that directly or indirectly pertain to the manufacture of the Product or other Product-related documentation as otherwise agreed in writing between the Parties.

2.20 Safety and Efficacy Notification and Claims. The NOVASEP Project Manager or Project Team members will be responsible for promptly notifying CUSTOMER of any information of notice of which it becomes aware concerning the safety or efficacy claims of the Product (or the manufacture process of the Product), including any threatened or pending action by any governmental or regulatory authority relating thereto. CUSTOMER shall be responsible for handling all such complaints and NOVASEP will cooperate in resolving any such complaints at CUSTOMER's request.

2.21 Accident Reports. To the extent permitted by law, each Party will report to the other, as soon as possible, all material accidents related to the manufacture, handling, use or storage of any Raw Materials or Product, including, without limitation, accidents resulting in; (i) personal injury requiring more than first aid treatment; (ii) chronic illness or loss of consciousness; (iii) material property damage; (iv) material environmental release; and (v) regulatory, safety, health or environmental audits.

2.22 Audit. Maximum once a year per Product, CUSTOMER may conduct (or have conducted on its behalf) on-site compliance quality audits of NOVASEP to inspect areas, equipment (including Equipment) and materials (including Materials and Products), the Facility, including procedures and data connected with a Work Plan and any packaging, testing or storage of any Product NOVASEP shall receive prior reasonable notice of such audit at least twenty (20) business days in advance, in order to make relevant staff available to attend the audit and comply with any reasonable requests of CUSTOMER. Such audit shall take place during normal business hours. CUSTOMER shall use its reasonable endeavors not to cause any disruption to NOVASEP's business and activity in carrying out such audit in the event that the audit under this Section extends beyond two (2) business days, NOVASEP will charge CUSTOMER a per diem of [**] which shall include reasonable access to NOVASEP's qualified and experienced employees. For the avoidance of doubt, such right of CUSTOMER does not include any right to inspect or audit NOVASEP's financial data or accounting records.

2.23 For Cause Audit. Without limitation and restriction in time, CUSTOMER may, immediately upon request, conduct compliance quality audits of NOVASEP to inspect areas, equipment and materials of the Facility where the Work is performed and records relating to the Work, where there has been any material breach of any obligation hereunder or of the Quality Agreements or there are circumstances giving rise to a reasonable concern of non-compliance with this Agreement, cGMP or any regulatory obligations.

2.24 Regulatory Audit. In addition to the annual audit, CUSTOMER shall be entitled to request, authorize or conduct (or have it done on its behalf) any necessary additional audit required pursuant to any notification from a governmental or regulatory authority to conduct an inspection of the Facility (or other facility) used in the development, manufacturing, storage or handling of the Product. Under such circumstances, NOVASEP will, without charge, permit governmental or regulatory authority bodies (together with CUSTOMER's designated representatives) to enter those areas of NOVASEP premises (including the Facility) used for the performance of the Works for the purpose of observing and inspecting the performance of the Works and those records of NOVASEP specific to the Works. During any such regulatory inspections, NOVASEP will provide reasonable assistance as requested by the relevant governmental or regulatory authority and shall promptly permit access to and copy and verify records and reports in NOVASEP's

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possession, custody or control relating to the Works. In addition to the above, NOVASEP shall immediately notify CUSTOMER of any audit or inspection undertaken at the Facility by any authority or regulatory body that raises any issues, deviations, defects, actions or concerns with respect to the operation of the Facility. NOVASEP's personnel or record keeping, and shall provide full details of the same to CUSTOMER together with the remedial plan and updates as to NOVASEP's progress to resolving all issues, deviations, defects, actions or concerns.

2.25 Other Services. If NOVASEP, at CUSTOMER's written request, provides assistance or services to CUSTOMER for the Importation of any raw materials, intermediates or substances, or for the exportation of the Product or any deliverable, such services will be invoiced by NOVASEP to CUSTOMER at a rate of [**]

2.26 Technology Transfer. Upon (i) a material breach of this Agreement (including any Work Plan) by NOVASEP; and/or (ii) NOVASEP falling to comply with Good Industry Practice and/or use Reasonable Endeavours regarding the Delivery of a Product to CUSTOMER as required in a Work Plan, and/or (iii) mutual agreement between NOVASEP and CUSTOMER in writing that the Work or the applicable Work Plan lack technical feasibility; and/or (iv) three (3) failures by NOVASEP in any eighteen (18) month period to deliver Batches in accordance with the relevant Specification and failure to replace the same in accordance with Section 3.6 of this Agreement notwithstanding the application by NOVASEP of Reasonable Endeavours with respect thereto; and/or (v) NOVASEP advising CUSTOMER in writing that it does not have capacity to perform the Work in any Work Plan within a reasonable timeframe or to meet CUSTOMER's reasonable capacity requirements; and/or (vi) NOVASEP seeking to vary the terms of any Work Plan or any Price beyond what would reasonably be deemed to be reasonable commercial terms; and/or (vii) Upon any change of control of NOVASEP or any Affiliate controlling it (control having the meaning as defined in the definition of Affiliate) [**] and/or (viii) CUSTOMER's request at any time until twelve (12) months after the last of the Works has been completed, on a Work Plan by Work Plan basis but subject to payment, [**] to those costs budgeted by NOVASEP for the technology transfer activities, as pre-agreed by CUSTOMER, to a maximum fee of [**] have signed a commercial agreement providing funding for the construction or a NOVASEP commercial viral vector manufacturing facility (save that such fee shall not be payable if such transfer is to a NOVASEP facility) [**] reasonable, pre approved and properly incurred cost of the technology transfer [**] the event that no such agreement has been signed between [**]; CUSTOMER may by written notice to NOVASEP require NOVASEP to provide assistance for the technology transfer to CUSTOMER or any other person at CUSTOMER's direction of the manufacturing process and technology relating to the Product to enable the manufacture of the Product at a different facility and by a different person. Following NOVASEP's receipt of such notice, the Parties will establish, in good faith, a schedule and plan for such transfer (including the security and preservation of all NOVASEP Confidential Information) and NOVASEP will thereafter co-operate with and provide all assistance requested by CUSTOMER in Implementing and effecting such transfer, including by the provision of NOVASEP's personnel and NOVASEP will also make available, subject to any regulatory obligations, all CUSTOMER Materials, and at least one (1) copy of all documentation generated pursuant to the performance of the Work up to the date of termination or expiry, including (without limitation) Batch Records, development reports and production process documentation, in addition to any applicable fee provided pursuant to Section 2.26 (vii), the reasonable, pre-approved costs of such transfer will be borne by CUSTOMER save where the transfer is required or the agreement is terminated as a result of any material breach of this Agreement by NOVASEP.

2.27 Variable Costs. The costs of Raw Materials and other consumables, disposables and reagents required for conducting the process to manufacture such Product in accordance with the standards and obligations of this Agreement (for example but without limitation, culture media, chromatographic resins, membranes and filters) (together the "Variable Costs") will be estimated by NOVASEP, as accurately as possible, in the applicable Work Plan. NOVASEP will use Reasonable Endeavours not to exceed the estimated Variable Costs per Work Plan. Where not included in the Price. NOVASEP will invoice CUSTOMER the actual and properly incurred Variable Costs incurred by NOVASEP in compliance with this Agreement with any overhead charges not to [**] of the Variable Cost paid by NOVASEP, and CUSTOMER will pay such invoice in accordance with the payment provisions in Section 9.1. in the event that actual and property incurred Variable Costs are likely to exceed the estimate set out in the relevant Work Plan, NOVASEP will notify CUSTOMER and obtain CUSTOMER's prior written approval in advance of incurring such increased Variable Costs (and provided they will be reasonably and necessarily incurred) and will use its best endeavours to reduce the increase in Variable Costs. Provided CUSTOMER has approved such increased Variable Costs in advance, NOVASEP shall invoice CUSTOMER for these additional costs with any overhead charges not [**] the Variable Cost paid by NOVASEP. Should the Variable Costs borne by NOVASEP at the expiration or termination of the relevant Work Package or Work Plan be less than the amount invoiced, then the difference shall be refunded to CUSTOMER.

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3 CUSTOMER's obligations, Supplies and Delivery

3.1 **General obligation of CUSTOMER.** As a general obligation, CUSTOMER shall perform the tasks assigned to it as defined in this Agreement or as set out in a Work Plan. CUSTOMER shall also supply NOVASEP sufficiently in advance with such materials. Information and documents as NOVASEP may reasonably request for the proper performance of its obligations hereunder, as more specifically described in a Work Plan. CUSTOMER shall also take delivery of the Product manufactured by NOVASEP at NOVASEP's Facility and Results within seven (7) days following NOVASEP's notice of readiness to CUSTOMER.

3.2 **Packaging.** All Product and Results to be Delivered to CUSTOMER shall be packaged by NOVASEP in accordance with those agreed and applicable packaging standard operating procedures and the Specification.

3.3 **Delivery.** All Product and Results shall be delivered to CUSTOMER FCA NOVASEP Facility In-Belgium (incoterms 2010 of the ICC) ("Delivered" or "Delivery" as applicable). Transportation and insurance costs in respect of the Delivery shall be borne by CUSTOMER. For the avoidance of doubt should NOVASEP provide assistance to CUSTOMER (at CUSTOMER's express written request) for the organization of the shipment of the Product and/or the Results and/or choose the shipping agents and companies on behalf of CUSTOMER NOVASEP will not be responsible or liable for damages or loss that could occur to the Product and/or Results during Delivery as a consequence of that assistance. NOVASEP will provide CUSTOMER with advance notice of the anticipated date of Delivery and shall endeavor to provide the Results as early as possible prior to the date of Delivery of the Product. All Batch Records and Results shall be delivered by mail or electronic mail to CUSTOMER.

3.4 **Non-Certified Delivery.** Subject to any mandatory regulatory requirements relevant to the manufacture of cGMP Product for human use and other cGMP compliance, CUSTOMER may, by written notice, request following NOVASEP's quality department having reviewed the relevant Batch Records and any eventual deviations (to be carried out no later than ten (10) business days following receipt of such notice from CUSTOMER), that NOVASEP Delivers partially manufactured Product under quarantine status to CUSTOMER prior to NOVASEP issuing a Certificate of Analysis or prior to NOVASEP providing all documents in accordance with Section 3.4, to the extent required to perform an additional Product manufacturing step such as labelling or packaging ("Non-Certified Delivery") Notwithstanding such request and delivery, NOVASEP shall thereafter provide a Certificate of Analysis and all documents required pursuant to Section 3.3 of this Agreement.

3.5 **Examination of Products for Defects.** CUSTOMER shall examine and test Products delivered for (i) defect and non-conformity with any applicable specifications or cGMP standards which they are specified to meet and (ii) in the case of Product manufactured to Specification and released with a Certificate of Analysis, review the Batch Records to assess whether the Product fails to meet Specification (a "Defect") Where any Defect is identified CUSTOMER shall notify NOVASEP by written notice ("Defect Notice") in accordance with the following timetable, (i) within ten (10) days of collection following Delivery of any visual (to the naked eye) Defect, (ii) within thirty (30) days of receipt by CUSTOMER of documented Products (including, without limitation, Batch Records) of any errors in any such documented Products provided that NOVASEP provides timely answers to information requests and resolution of issues arising from CUSTOMER's review of such Products, and (iii) within ten (10) business days of discovery by CUSTOMER of any other defect including any defect which results from non conformity with NOVASEP's warranties or which existed when the Batch was delivered to CUSTOMER but was not discoverable by review of the Batch Records during the thirty (30) days after CUSTOMER's receipt of the Batch Records. Following service of a Defect Notice, NOVASEP will arrange with CUSTOMER to collect any Products which are the subject of the Defect Notice within ten (10) business days NOVASEP will promptly react to the Defect Notice and investigate the occurrence of and reasons for the Defect and shall report to the Project Team within twenty (20) business days of receipt, its findings and whether it accepts or disputes (in whole or part) responsibility for the Defect Should any Batch that is the subject of a Defect be subsequently re-certified by NOVASEP, NOVASEP shall ensure such Batch meets the Specification and conforms with the Certificate of Analysis.

3.6 **Consequences of Defective Product.** Where the Defect is, as between NOVASEP and CUSTOMER, substantially due to NOVASEP (or its Affiliates' or contractors') acts, omissions or breach of its obligations under this Agreement, (including where such acts and omissions or breaches could be, but are not limited, to operator mistakes equipment failure, power shortages and building environmental control failures) or where the Specification of a Batch is not met when the Parties have agreed that such Specification should be bidding with regards to a particular Batch, NOVASEP shall (i) use all Reasonable Endeavours to replace at its own cost and as soon as reasonably practicable (and in any event within one hundred and ninety (190) business days of the Defect notice) an equal quantity of Product free of defects as that which was Defective; and (ii) pay all expenses, fees and charges associated with the

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manufacture and return of the defective Product, and (iii) reimburse CUSTOMER (subject to Sections 12.3 and 12.4 of this Agreement) for any reasonably Incurred or foreseeable costs incurred by CUSTOMER (and which could not be refunded to CUSTOMER), as a result of the Products being defective. The Parties agree and acknowledge that any samples held by NOVASEP from the manufacturing run pursuant to the terms of this Agreement including the Product that is Defective shall be made available for testing purposes in the event any Product is Defective. Any disputes regarding a Defect or calculating the appropriate refund of monies shall be referred to an Independent expert, reasonably acceptable to and appointed by both Parties and subject to confidentiality provisions comparable to those set out in this Agreement, The independent expert shall undertake the relevant analysts to assess whether the Product was defective and whether NOVASEP was responsible in any way. Both Parties agree to cooperate with the independent expert's reasonable requests for assistance in connection with its analysis hereunder. The independent expert shall act as an expert and not arbitrator. The decision of the independent expert shall be written and given in English and be considered final and binding on the Parties unless there has been a manifest error on the face or the decision whereupon the Parties shall revert to the dispute resolution procedure in this Agreement. The fees and expenses of such expert shall be borne in full by the Party against whom the Independent expert decides.

4 NOVASEP's warranties

4.1 NOVASEP warrants and undertakes to CUSTOMER that;

- (a) the Work will be conducted in a diligent and professional manner with professional skill and care and in accordance with cGMP. all applicable laws and otherwise in accordance with the terms of this Agreement;
- (b) NOVASEP will not knowingly Infringe or misuse any third party intellectual Property Rights in its performance of the Work;
- (c) NOVASEP has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary of a biologics contract manufacturer for the regular provision of manufacturing and development services of biologic material;
- (d) the Facility shall be maintained in accordance with cGMP and all other applicable laws and regulations in such condition as will allow NOVASEP to manufacture the Product in compliance with cGMP, all other applicable laws and regulations, to meet the Specification and in conformance with the Master Production Record, and
- (e) all Product (i) and Results shall be Delivered free of encumbrances of liens; (ii) shall be manufactured and analyzed in conformance with the Master Production Record; (iii) shall be manufactured in compliance with the requirements of cGMP and all other applicable laws and regulations; (iv) shall be packaged in accordance with the shipping guidelines; (v) shall conform, at the time of delivery, to the Specification, and (vi) where Product is released with a Certificate of Analysis, the Product will comply with the criteria specified in that Certificate of Analysis,

4.2 Except as expressly otherwise stated in this Agreement, NOVASEP expressly excludes and disclaims all other warranties (whether implied or express), including, without limitation; (i) any warranty of merchantability or (ii) any warranty of fitness of the Products and deliverables supplied under this Agreement for the particular purpose for which CUSTOMER intends to use them.

5. CUSTOMER's Warranties

5.1 CUSTOMER warrants and undertakes that to its knowledge any Customer Background Data, Materials, Equipment and Product which NOVASEP is required by CUSTOMER to use, access or modify is legally licensed to CUSTOMER or is CUSTOMER's own property, and that to its knowledge NOVASEP's use of Customer Background Data, Equipment, Product and Materials for those activities performed in accordance with the terms of this Agreement will not infringe the rights (including without limitation the intellectual Property Rights) of any third parties.

5.2 CUSTOMER warrants and represents to NOVASEP that the nature of the Materials and Product delivered by or on behalf of CUSTOMER to NOVASEP will conform to all relevant legal requirements.

5.3 CUSTOMER warrants and represents to NOVASEP that the nature of the Materials and Product delivered by or on behalf of CUSTOMER to NOVASEP will, so far as if is aware, be free of hazardous or toxic material unless clearly specified for known hazardous

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materials such as cytostatic/cytotoxic materials, Material Safety Data Sheets and any specific safe material handling instructions applicable to the Materials and Product will be disclosed by CUSTOMER in advance to NOVASEP in writing and Included with shipments Before the beginning of the Work, CUSTOMER shall supply NOVASEP free of charge with copies of all safety information relating to the Materials and Product.

6 Intellectual Property Rights

6.1 Pre-Existing Intellectual Property. Any Intellectual Property Rights owned by a Party or licensed by a third party to a Party as of the Effective Date or before the commencement of the applicable Work Plan (“**Pre-Exiting IPR**”) and as detailed in the schedules at Parts 6 and 7 for CUSTOMER Pre-Existing IPR and NOVASEP Pre-Existing IPR respectively, shall remain the sole and absolute property of the Party that owned or was licensed to use such Pre-Existing IPR. Nothing in this Agreement shall act as any assignment or transfer of the Pre-Existing IPR of either Party nor, save as expressly set out herein, any licence to any Party’s Pre-Existing IPR.

6.2 Intellectual Property Rights created in the course of performing the Work. All Results and Work Plan IP that comprises (i) any improvement or enhancement to, or that is developed through the use of CUSTOMER’s Pre-Existing IPR and/or (ii) any Upstream Results which incorporate, use, relate to, or arise from use of, any of the [**] and Irrespective of whether (i) or (ii) are generated alone by either Party or jointly between the Parties shall be owned solely by CUSTOMER (“CUSTOMER Foreground IPR”) and title to CUSTOMER Foreground IPR will pass to CUSTOMER immediately on creation. All Results (including without limitation Downstream Results) and Work Plan IP that is not CUSTOMER Foreground IPR and specifically relates to NOVASEP’s Pre-Existing IPR, whether generated alone by either Party or jointly between the Parties shall be owned solely by NOVASEP (“NOVASEP Foreground IPR”) and title to NOVASEP Foreground IPR will pass to NOVASEP immediately on creation, NOVASEP will disclose to CUSTOMER, at the end of each Work Plan and via the Project Team, all Results comprised in NOVASEP Foreground IPR, any new NOVASEP Foreground IPR which was not previously used or disclosed in respect of the relevant Work Plan and CUSTOMER Foreground IPR generated in respect of the relevant Work Plan, For the avoidance of doubt, such disclosure will be subject to the confidentiality provisions set out in this Agreement. All Results and Work Plan IP which is not CUSTOMER Foreground IPR or NOVASEP Foreground IPR, whether generated alone by either Party or jointly between the Parties, shall be jointly owned in equal undivided shares by the Parties (“Jointly Owned Foreground IPR”), disclosed to CUSTOMER on creation (to the extent not already in CUSTOMER’s possession) and held subject to the terms of this Agreement.

6.3 Grant of Intellectual Property License for the performance of the Work. Each Party hereby grants to the other for the Term a non-exclusive, royalty-free, sub-licensable limited licence in respect of their respective Pre-Existing IPR and Foreground IPR solely to the extent the same is required and necessary for the proper performance of the Work, on a Work Plan by Work Plan basis. This license (i) does not prevent the Party granting the licence from making any use of its own Pre-Existing IPR or Foreground IPR; and (ii) subject to Section 6.4 of this Agreement, terminates automatically upon the expiry of the applicable Work Plan or termination of this Agreement, whichever is the earlier. For the avoidance of doubt, the licence granted by this Section in respect of CUSTOMER’s Pre-Existing IPR and Foreground IPR does not include any Intellectual Property Rights licensed by a third party to CUSTOMER and which may be included in CUSTOMER’s Pre-Existing IPR and/or CUSTOMER’s Foreground IPR but in respect of which CUSTOMER has not been granted a license to sub-license or otherwise transfer such third party Intellectual Property Rights.

6.4 License in respect of Intellectual Property Rights in Upstream Results. In respect of Intellectual Property Rights in the Upstream Results that; pursuant to Section 6.2 of this Agreement, are part of CUSTOMER Foreground IPR, CUSTOMER hereby grants to NOVASEP, a perpetual, non-exclusive, royalty-free, worldwide license, sub-licensable (through one tier) to its Affiliates and to its other customers, commencing at the end of the first Work Plan, in respect of such Upstream Results, for any use outside the Field. For licences through subsequent tiers the Parties shall enter into good faith and timely efforts to agree the terms of any such licences on reasonable commercial terms. For the avoidance of doubt, NOVASEP will not be in breach of its confidentiality obligations under this Agreement by exercising its rights granted pursuant to this license provided that any disclosure made by NOVASEP is only under obligations of confidentiality consistent with those herein and disclosures are only to its sub-licensees and are necessary for NOVASEP to exercise the rights granted to it pursuant to this license.

For clarity, CUSTOMER hereby agrees and covenants that, provided that NOVASEP does not breach its confidentiality, non-use or any other obligations herein and otherwise complies with this Agreement, it shall not prevent NOVASEP (including without limitation any of NOVASEP’s employees involved in the performance of the work) from performing work similar to the Work, for and/or with any third party, which includes the use [**] which is independently developed by NOVASEP or licensed or otherwise provided to NOVASEP by a third party. For the avoidance of doubt, NOVASEP shall not use any [**] provided of developed by or on behalf of CUSTOMER for any purpose in respect of any third party other than CUSTOMER other than as permitted under this Agreement.

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6.5 **License to NOVASEP Intellectual Property Rights.** NOVASEP hereby grants to CUSTOMER a non-exclusive, perpetual, irrevocable, royalty free, fully paid, worldwide fully transferable license (with the right to grant and authorise the granting of sublicenses through multiple tiers) to use and (and in accordance with the provisions of Section 8.4 of this Agreement) disclose the NOVASEP intellectual Property Rights to the extent that the same is necessary to enable CUSTOMER and/or any of its licensees or subcontractors to (i) manufacture the Products; (ii) include such NOVASEP Intellectual Property Rights within any Regulatory Filings; and (iii) to use and disclose such NOVASEP intellectual Property Rights in conjunction with the labelling, marketing and sale of any Products. "NOVASEP Intellectual Property Rights" for the purposes of this Section 6.5 only means those intellectual Property Rights owned by or licensed to NOVASEP including NOVASEP Foreground IPR and any intellectual Property Rights in the Batch Records. This license shall survive the termination or expiry of this Agreement for any reason.

6.6 **Further Assurance and Right to file for protection.** NOVASEP shall promptly notify CUSTOMER of all CUSTOMER Foreground IPR developed hereunder and shall promptly do all acts and execute all documents and deeds reasonably necessary to vest in CUSTOMER the rights assigned or to be assigned to CUSTOMER pursuant to Section 6.2, of this Agreement. CUSTOMER may file patent protection on any intellectual Property Rights it owns in accordance with Section 6.2 of this Agreement and NOVASEP shall promptly upon request co-operate at CUSTOMER's reasonable expense, with any requests to assist or enable CUSTOMER's protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

CUSTOMER shall promptly notify NOVASEP of all NOVASEP Foreground IPR developed by CUSTOMER hereunder and shall promptly do all acts and execute all documents and deeds reasonably necessary to vest in NOVASEP the rights assigned or to be assigned to NOVASEP pursuant to Section 6.2 NOVASEP may file patent protection on any intellectual Property Rights it owns in accordance with Section 6.2 of this Agreement and CUSTOMER shall promptly upon request co-operate at NOVASEP's reasonable expense, with any requests to assist or enable NOVASEP's protection including but not limited to signing and delivering documents and other information necessary for the valid application and prosecution of any such patent.

6.7 Jointly Owned Intellectual Property Rights.

(a) Each Party shall promptly notify the other Party of all Jointly Owned Foreground IPR developed by that Party in accordance with Section 6.2 of this Agreement and the Parties will cooperate to promptly do all acts and execute all documents and deeds reasonably necessary to vest in both Parties the equal right to such Jointly Owned Foreground IPR, the costs of which shall be borne equally by both Parties.

(b) NOVASEP and CUSTOMER will be jointly responsible for agreeing and applying for protection for, and all filing, prosecution (including opposition), and maintenance with respect to, the intellectual Property Rights in the Jointly Owned Foreground IPR in all territories and countries agreed in writing between the Parties (the "**Joint IP Rights**"), Prosecution of such Joint IP Rights shall be [**] using patent counsel [**] NOVASEP and CUSTOMER shall cooperate in the preparation, filing, prosecution, and maintenance of all Joint IP Rights, Cooperation includes, without limitation, (i) consulting with the other Party as to the preparation, filing, prosecution, and maintenance of all Intellectual Property Rights reasonably prior to any deadline or action of any patent office, (ii) furnishing the other Party with all relevant documents reasonably in advance of filing, and including in such documents in good faith the comments thereon of the other Party, (iii) promptly executing all papers and instruments or requiring employees to execute papers and instruments as reasonable and appropriate; and (iv) informing the other Party of matters that may affect the preparation, filing, prosecution, or maintenance of any intellectual Property Rights Costs and expenses (beyond those of the Parties' own internal resources) relating to such filing, prosecution and maintenance of Joint IP Rights shall be [**]

(c) All decisions with respect to the enforcement of Joint IP Rights shall be made jointly by mutual agreement of the Parties. Each Party shall bear [**] for such enforcement as well as any adverse costs award made in connection with such enforcement.

(d) A Party may by written notice unilaterally surrender to the other Party all of its rights and obligations to all or any portion of the Joint IP Rights upon fifteen (15) days' written notice. in the event that a Party has given notice of its surrender of its rights and obligations to all or any portion of the Joint IP Rights (the "**Surrendering Party**"), from expiry of the notice the other Party shall become the sole owner of such Joint IP Rights (the "**Surrendered Joint IP Rights**") and thereafter have the sole discretion with respect to the

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filing, prosecution, maintenance and enforcement of the Surrendered Joint IP Rights Where the Surrendering Party gives notice to surrender its interest in any Joint IP Rights that are the subject of any enforcement action approved by the Parties pursuant to sub-section (c) above, the Surrendering Party shall [**] of such enforcement action unless or until the other Party releases it.

(e) The Surrendering Party hereby appoints the other Party to be its attorney to execute any such Instrument and/or do any such thing solely for the limited and explicit purpose of recording the other Party as the sole proprietor of, and for perfecting all legal and equitable title in, the Surrendered Joint IP Rights (including any Joint IP Rights that are the subject of any enforcement action approved by the Parties in respect of which the Surrendering Party has given notice to the other Party to surrender its interest in accordance with sub-sections (c) and (d) above) and for no other purposes. The power of attorney granted by this clause expressly includes, without limitation, the execution and/or recording (where applicable) of an assignment. In respect of such Surrendered Joint IP Rights. The Surrendering Party acknowledges in favour of a third party that a certificate in writing signed by any director or the secretary of the other Party having the limited effect provided for by this power to record the other Party as the proprietor of the Surrendered Joint IP Rights falls within the authority conferred by this Agreement and shall be conclusive evidence that such is the case. This power of attorney is irrevocable and shall survive termination of this Agreement or any Work Plan.

(f) **Mutual license in respect of Jointly Owned Foreground IPR.** Each Party hereby grants to the other Party a non-exclusive, perpetual, irrevocable, royalty free, fully paid, worldwide fully transferable license, sub-licensable through multiple tiers, to use and (subject to each Party's strict compliance with the provisions of Section 8 at all times) disclose the Jointly Owned Foreground IPR Notwithstanding the perpetual and Irrevocable nature of the foregoing licence, upon a Party becoming a Surrendering Party in respect of any Jointly Owned Foreground IPR in accordance with Sub-section (c) above or otherwise ceasing to have any ownership in respect or any Jointly Owned Foreground IPR, then this licence shall automatically terminate with respect to such Jointly Owned Foreground IPR. The provisions of this Section 6.7 survive the termination or expiry of this Agreement for any reason.

6.8 Party's Names. Except as otherwise provided for in this Agreement as agreed in writing between the Parties, or required by any applicable law, regulation or order of an administrative agency or court of competent jurisdiction, neither Party shall use the name of the other Party or of the other Party's directors, officers or employees in any advertising, news release or other publication.

6.9 Public Announcements. Except as required by applicable law, rule or regulation or any stock exchange on which securities issued by a Party or its Affiliates are traded, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed, provided that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 6.8 and which do not reveal non-public information about the other Party. For the avoidance of doubt, nothing in this clause (or otherwise in this Agreement) will prevent CUSTOMER from disclosing the fact that NOVASEP is the manufacturer of the Product, whether by disclosing such Information on Product packaging, labelling or documentation or to any of CUSTOMER's Affiliates, employees, licensees, customers, or to other bodies or individuals who may reasonably require such disclosure (including, for the avoidance of doubt, regulatory bodies) Such disclosure by CUSTOMER will not require NOVASEP's prior consent.

7 Future Cooperation

7.1 The Parties agree to explore, in good faith, the option for NOVASEP to plan and provide CUSTOMER with commercial scale manufacturing services of any Product specified in a Work Plan and the Parties respective investments and contributions to the necessary scale up such discussions to commence within three (3) calendar months from the Effective Date with respect to the Product which is the subject of the first Work Plan. For the avoidance of doubt, nothing in this Section 7 or otherwise in this Agreement shall bind CUSTOMER to engage NOVASEP in respect of commercial scale manufacturing services or as an equipment supplier, the engagement of which shall be at CUSTOMER's sole discretion.

7.2 Any refusal by CUSTOMER to engage NOVASEP in this regard will not adversely affect or otherwise prejudice CUSTOMER's receipt of services from NOVASEP and NOVASEP's performance of services and provision of Works as set out in any Work Plans.

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8 Confidentiality

8.1 The Receiving Party shall keep strictly confidential all Confidential Information it receives from or on behalf of the Disclosing Party and shall not disclose the same to a third party without prior written consent of the Disclosing Party.

8.2 The foregoing obligations of confidentiality and the restrictions on use below shall not apply to any portion of the Disclosing Party's Confidential Information that the Receiving Party can demonstrate by documentary evidence:

(a) was fully and lawfully already in its possession free of any confidentiality obligation prior to receipt from the Disclosing Party, or

(b) was wholly in the public domain at the time of receipt from the Disclosing Party and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence; or

(c) became part of the public domain through no fault of the Receiving Party, its Affiliates or any of its licensees or sub-contractors (as may be agreed to during the Term by the Disclosing Party pursuant to the terms of this Agreement) and whether directly or indirectly; or

(d) was lawfully received by the Receiving Party from a third party having a right of further disclosure and who did not, directly or Indirectly, receive such Confidential information from the Disclosing Party; or

(e) is required by law, regulation, rule, act, or order of any governmental authority or agency to be disclosed by the Receiving Party, provided, however, that the Receiving Party gives the Disclosing Party sufficient advance written notice to permit the Disclosing Party to seek a protective order or other similar order with respect to such Confidential Information and thereafter discloses only the minimum Confidential Information required to be disclosed in order to comply.

8.3 Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Information is embraced by general disclosures in the public domain or in the possession of the Receiving Party. In addition, any combination of Confidential information shall not be considered in the public domain or in the possession of the Receiving Party merely because Individual elements there of are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

8.4 Confidential Information of the Disclosing Party shall not be used by the Receiving Party other than for the purpose of this Agreement, the performance of the Works or as otherwise permitted to be used under or in accordance with the terms of this Agreement including under any licenses granted hereunder and those third parties envisaged in Section 6.5 (i) and (ii). The Parties shall only disclose Confidential information to employees, sub-licensees, sub-contractors (who have been pre approved by the Disclosing Party in advance) and/or Affiliates who have a genuine need to access such information in order to fulfil the Parties' obligations under this Agreement and/or to exercise the Party's rights under this Agreement. Where any Confidential Information may be sub licensed by a Party such Confidential information may be disclosed to such sub licensee and any potential sublicensees or to any Permitted Sub-contractors (who have been pre-approved by the Disclosing Party in advance) subject to confidentiality obligations no less onerous than those herein.

8.5 The Receiving Party agrees that, at the other Party's request; or upon expiration or termination of this Agreement (whatever the reason), the Receiving Party shall forthwith return to the other Party any and all parts of the Disclosing Party's Confidential information provided in documentary form and will return, destroy or permanently delete (at the Disclosing Party's election) any copies or other tangible embodiments thereof made by the Receiving Party; except for one copy that may be retained in a secure file for compliance purposes only.

8.6 For the purposes of this Section 8, the CUSTOMER Foreground IPR shall be treated as Confidential Information of CUSTOMER and the NOVASEP Foreground IPR shall be treated as Confidential Information of NOVASEP.

8.7 Neither Party shall, without the prior written consent of the other Party, disclose to any third party the terms of this Agreement (including any Work Plan), which shall be treated as Confidential Information, save that the Receiving Party may under obligations of confidentiality disclose this Agreement and relevant contents to its employees, directors, shareholders, Investors, and any potential Investors, sublicensees or shareholders and/or any of their professional advisors on a 'need to know' basis.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

8.8 The Receiving Party will ensure the proper and secure storage of all of the Disclosing Party's Confidential Information applying standards of care reasonably expected and no less stringent than standards applied to protection of the Recipient Party's own Confidential Information.

8.9 Other than the limited and restricted rights of use set out in this Section 8 or under any licences granted elsewhere in this Agreement, nothing in this Agreement intends to or has the effect of granting any right, title, licence or interest in or to the Receiving Party in respect of the Disclosing Party's Confidential Information.

8.10 These obligations of confidentiality and non-use are valid during the period of this Agreement and for a period of [**] years after its termination. Each Party agrees to indemnify the other from any loss suffered as a result of the violation of the provisions in this Section 8.

9 Fees and expenses

9.1 CUSTOMER shall pay NOVASEP all sums specified in a Work Plan together with any agreed Variable Costs properly incurred in accordance with Section 2.25 of this Agreement. Unless otherwise agreed, all Prices and Variable Costs (where applicable and agreed) are lump sum amounts and are inclusive of taxes, duties, levies, Value Added Tax, other fees of whatever nature imposed by or under the authority of any government or public authority and all other costs and expenses (including, without limitation, raw materials, duties or charges for transportation, insurance shipping, storage and custom clearance of the Product and the deliverables) that NOVASEP incurs to perform the Works which CUSTOMER agrees to pay in addition to the price for the Works as set out in the Work Plan, Such prices based on delivery being FCA NOVASEP's plant (Incoterms 2010 of the ICC). All down-payments made by CUSTOMER will be off-set against the applicable Price for the Works in case NOVASEP wishes to deliver to CUSTOMER any quantity of Product above foreseen or required quantities, as indicated in a Work Plan, CUSTOMER may accept Delivery of such greater quantity of Product but at no additional cost to CUSTOMER beyond the Price unless otherwise agreed between the Parties in writing.

9.2 CUSTOMER shall obtain at its own expense any export and import license or other official authorization and carry out all customs formalities necessary for the exportation and/or importation of the deliverables and NOVASEP shall assist CUSTOMER to the extent reasonable in applying for and obtaining such licenses, authorizations or formalities.

9.3 Subject to Section 2.13, NOVASEP shall issue invoices to CUSTOMER in Euros in respect of the Price in accordance with the terms of this Agreement and the amount and invoicing schedule set out in the relevant Work Plan and, in the absence of any such schedule or conflicting provision herein, within thirty (30) days following completion of the relevant Works for which any invoice is issued in accordance with Section 2.2 CUSTOMER will not be liable for the payment of any fees, charges and expenses not set out in a Work Plan or, agreed between the Parties in writing before being incurred.

9.4 All invoices issued in accordance with Section 9.3 that are not the subject of any bona fide dispute or query or subject to Section 9.5 shall be paid in full within thirty (30) days of the date the invoice is received by CUSTOMER. NOVASEP will be entitled, at its discretion to charge CUSTOMER a maximum interest at an annual rate of [**] above Bank of England base rate in respect of any late payment of outstanding sums due in respect of work agreed by both Parties as being completed and satisfactory.

9.5 If CUSTOMER serves a Defect Notice or otherwise rejects any delivery of product, CUSTOMER shall not be required to pay any invoice with respect thereto until the later of (i) thirty (30) days after such Product is finally determined not to be Defective Product: or (ii) thirty (30) days after delivery by NOVASEP of replacement Product, as applicable.

9.6 The performance of the Work by NOVASEP may be subject to change in laws and regulations, in particular (but not only) as a result of the application of the European REACH regulation (1907/2006). For any proposed change in legislation which the Parties identify as likely to have a potential impact on costs for NOVASEP in respect of its manufacture of the Product (and not in respect of any other products or any other work NOVASEP may be undertaking in respect of any other party), the Project Team and/or Steering Group (as applicable) will discuss how the Parties can mitigate the risk of increased costs in advance of any such change to legislation coming into force. Provided that the Parties comply with the terms of this Section 9 and that increased costs for NOVASEP arise exclusively as result of the Work (and not any work Undertaken for or on behalf of any third party), any such reasonable costs which have been pre-approved by CUSTOMER will be borne by CUSTOMER.

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9.7 All payments to NOVASEP pursuant to this Agreement shall, unless specified otherwise in a Work Plan or varied by written notice to CUSTOMER prior to CUSTOMER's receipt of an invoice under this Section 9, be made by bank transfer to the following bank account;

HENOGEN S.A
rue des Professeurs Jeener at Brachet 12
6041 Gosselles
Belgium
TVA [**]
Bank name [**]
IBAN [**]
BIC/SWIFT [**]

10 Term end Termination

10.1 This Agreement shall commence on the Effective Date, and shall continue (subject to earlier termination in accordance with this Agreement) in accordance with the time frame set forth in each Work Plan, and expire when the last of the Works is completed, unless otherwise agreed between the Parties (the "Term")

10.2 Either Party (the "**Non Defaulting Party**") may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to the other Party (the "**Defaulting Party**") if:

- (a) the Defaulting Party is in material breach of this Agreement (including any of its obligations under a Work Plan) provided that such breach (where capable of remedy) has not been remedied within [**] of receipt of written notice from the terminating Party specifying the breach;
- (b) the Defaulting Party is (a) generally unable to pay its debts as they become due; or (ii) has an administrator appointed or administration order made against it or an order for winding-up or dissolution made (otherwise than in the course of a bona fide reorganization previously approved in writing by the Non Defaulting Party) or liquidator appointed and such step is not withdrawn within 30 days; or
- (c) any permit or regulatory license is permanently revoked preventing the performance of the services or completion of the Works by the Defaulting Party.

10.3 CUSTOMER may terminate this Agreement before expiry of the Term with immediate effect upon prior written notice to NOVASEP in the event of a change of control of NOVASEP or any Affiliate controlling it (control having the meaning set out in the definition of Affiliate) whereby NOVASEP or such controlling Affiliate becomes controlled by a Competitor of CUSTOMER.

10.4 In addition to this, CUSTOMER may terminate this Agreement or any element of the Works or a Work Plan for any reason with a prior written notice of at [**] detailing which (or all) of the Works, a Work Plan are to be terminated or this Agreement in its entirety subject to the provisions of Section 11.2 of this Agreement.

11 Effect of Termination

11.1 On the termination or expiration of this Agreement CUSTOMER shall in accordance with this Agreement pay NOVASEP for all unpaid fees and expenses accrued in accordance with the terms of this Agreement up to the date of termination or expiration Each Party shall promptly return all Confidential information of the other Party, save that:

- (a) Both parties may retain one (1) copy for the purpose of monitoring its confidentiality undertaking as defined in this Agreement, and
- (b) CUSTOMER may retain one (1) copy of [**] and
- (c) NOVASEP may retain one (1) copy of [**]

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Within [**] of the termination or expiration of this Agreement NOVASEP shall deliver to CUSTOMER all CUSTOMER Equipment under the conditions provided for in Section 2.4, any remaining quantity of Customer Materials and/or Product already manufactured by or on behalf of NOVASEP and paid for by CUSTOMER.

11.2 If the Agreement has been terminated by CUSTOMER for convenience in accordance with Section 10.4 above, CUSTOMER shall pay NOVASEP for [**]

11.3 The provisions of Sections [**] will survive expiry or termination of this Agreement.

12 Liability

12.1 Each Party shall indemnify the other and hold the other harmless from and against any and all liability for death, illness or injury to any third party or for loss or damage to any third party's property and against all claims, demands, proceedings and causes of action (collectively, the "Liabilities") resulting directly or indirectly therefrom and arising out of a third party claim (a "Claim") arising from each Party's activities in the performance of the Work and/or arising out of any negligent or wrongful act or default on the part of the Party or its employees in the performance of or in compliance with any of their obligations under this Agreement, except as and to the extent any such Liabilities arise out of or results of the other Party's activities. In the performance of the Work and/or arising out of any negligent or wrongful act or default on the part of the other Party or its employees in the performance of or in compliance with any of their obligations under this Agreement.

12.2 Additionally, CUSTOMER shall indemnify and hold NOVASEP, its Affiliates, and their respective directors, officers, employees and agents harmless from and against all Liabilities resulting directly or indirectly therefrom and arising out of a Claim arising out of, resulting from or related to activities performed by CUSTOMER in connection with the Drug Product and/or the Drug Substance, save to the extent any Liabilities and Claims arise from or are caused by any breach by NOVASEP of this Agreement or are the subject of NOVASEP's obligations to indemnify CUSTOMER pursuant to Section 12.1 above.

12.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOSSES OF PROFITS). WHETHER IN CONTRACT OR IN TORT, UNDER INDEMNITY, OR OTHERWISE ARISING OUT OF ANY TERMS OR CONDITIONS IN THIS AGREEMENT OR WITH RESPECT TO THE PERFORMANCE THERETO, EXCEPT IN CASE OF GROSS NEGLIGENCE OR WILFUL MISCONDUCT, OR MISUSE BY OR ON BEHALF OF A PARTY OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OTHER THAN WHEN NOVASEP IS ACTING IN ACCORDANCE WITH THE INSTRUCTIONS OF CUSTOMER BUT SUBJECT TO NOVASEP NOTIFYING CUSTOMER OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OF WHICH NOVASEP MAY OR SHOULD BE AWARE USING REASONABLE ENDEAVOURS AND/OR WHICH MAY IMPACT ON SUCH INSTRUCTIONS, OR USING CUSTOMER BACKGROUND DATA, CUSTOMER PRE-EXISTING IPR OR CUSTOMER FOREGROUND IPR.

12.4 NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, THE LIABILITY OF NOVASEP ARISING OUT OF ANY TERMS OR CONDITIONS IN THIS AGREEMENT OR WITH RESPECT TO THE PERFORMANCE THERETO. BUT EXCLUDING ANY INFRINGEMENT OR MISUSE BY OR ON BEHALF OF NOVASEP OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS IN ITS PERFORMANCE OF THE WORK (OTHER THAN WHEN NOVASEP IS ACTING IN ACCORDANCE WITH THE INSTRUCTIONS OF CUSTOMER BUT SUBJECT TO NOVASEP NOTIFYING CUSTOMER OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS OF WHICH NOVASEP MAY OR SHOULD BE AWARE USING REASONABLE ENDEAVOURS AND/OR WHICH MAY IMPACT ON SUCH INSTRUCTIONS, OR USING CUSTOMER BACKGROUND DATA, CUSTOMER PRE-EXISTING IPR OR CUSTOMER FOREGROUND IPR). SHALL BE LIMITED TO [**]

13 Applicable Law – Dispute Resolution

13.1 This Agreement shall be entirely and exclusively interpreted and enforced in accordance with the laws of England.

13.2 In case of disputes between the Parties arising from the enforcement and/or the interpretation of the Agreement, the Parties shall try to settle amicably rapidly such dispute by the Steering Group, and failing that by discussions between the CEO of each

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Party. It is expressly agreed between the Parties that If no settlement can be found between them within a reasonable period of time, and in any case no later than two (2) months following the receipt by one Party of the written claim of the other Party, any disputes shall be brought in the Courts of England, which shall have exclusive Jurisdiction.

13.3 In case of disputes between the Parties arising from a Work Plan (or either Party's performance or non-performance of its obligations in respect of a Work Plan), the Parties shall try to settle amicably and rapidly such dispute by the Project Team. Disputes relating to a Work Plan that are not resolved by the Project Team within two (2) weeks of first notification will be escalated for resolution by the Steering Group and, where unsuccessfully resolved by the Steering Group within two (2) weeks of escalation from the Project Team, for discussion between the Chief Executive Officers of each Party. Disputes under this Section 13.3 not resolved amicably by the Chief Executive Officers in writing within one (1) week of the dispute being escalated from the Steering Group will finally be settled by the Courts of England.

13.4 In the event that either Party requires emergency relief in respect of a dispute, either Party shall be entitled to resort to litigation without observing the provisions regarding amicable dispute resolution in Sections 13.2 and 13.3.

14 Force Majeure

14.1 In this Agreement, Force Majeure means in relation to either Party, any circumstances beyond the reasonable control of that Party or rendering the performance by either Party impracticable due to the occurrence of a contingency the occurrence of which was not reasonably foreseeable at the time of contracting.

14.2 The following events are notably (but not exclusively) considered as events of Force Majeure: war (whether or not declared), revolutions, riot or civil commotion, accident (beyond reasonable control), fire (beyond reasonable control), explosions (beyond reasonable control), Flood (beyond reasonable control), storm, and other exceptional and unexpected events beyond all reasonable control of either party.

14.3 If any Force Majeure occurs in relation to either Party which affects or may affect the performance of any of its obligations under this Agreement, it shall notify the other Party forthwith as to the nature and extent of the circumstances in question.

14.4 Neither Party shall be deemed to be in breach of this Agreement, or shall be otherwise liable to the other Party, by reason only of any delay in performance, or the non performance of any of its obligations hereunder, to the extent that the delay or non performance is due to any Force Majeure of which it has duly notified the other Party, and the time for performance of that obligation shall be extended accordingly.

14.5 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by force Majeure for a continuous period in excess of ten (10) working days, the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

14.6 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for ninety (90) days or more, consecutively or cumulatively, in any one (1) year, then the other Party shall in its discretion have the right to terminate this Agreement forthwith upon written notice.

15 General

15.1 This Agreement is binding upon and for the benefit of the undersigned Parties, their successors and assigns. The Parties are not entitled to assign or sub-contract any of their obligations under this Agreement without the other Party's prior written consent, except as expressly permitted hereunder or otherwise in case of subcontracting, transfer or assignment to one of their Affiliates.

15.2 Each party is an independent contractor and neither is the agent of the other. Nothing in this Agreement is intended to or shall operate to create a partnership or joint venture or any kind between the Parties and no Party shall have authority to act in the name or on behalf of or otherwise to bind the other in any way.

15.3 If any provisions of this Agreement shall be held by a court of competent Jurisdiction to be Illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect. In such event, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision within the limits of applicable law or applicable court decisions.

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15.4 It is understood and agreed between the Parties that no failure or delay by a Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

15.5 This Agreement, along with its appendices, if any constitute the entire agreement between the Parties with respect to the subject matter hereof, and it is expressly agreed that any and all prior understandings or agreements between the Parties relating to the subject matter of this Agreement, whether oral or written, are automatically cancelled by the execution of this Agreement in the event that any term in this Agreement conflicts with any term in a Work Plan or any Quality Agreement (except in respect of matters concerning cGMP responsibilities and processes, in which case, the terms of any Quality Agreement would prevail), the conflicting term of this Agreement will prevail.

15.6 The terms and conditions set forth in the Agreement and its appendices (including any amendment to a Work Plan) may only be modified in a subsequent writing signed by the Parties.

15.7 All notices to be given under the Agreement shall be in writing in English and left at or sent by first class registered or recorded delivery mail, or fax to the appropriate address shown in Section 15.8 or left at or sent to such other address as the Party concerned may from time to time designate by notice pursuant hereto.

15.8 The Parties' contact information is:

For NOVASEP: [**]
CEO HENOGEN SA
12 rue des Professors Jeener et Brachet
B-6041 Charleroi, Belgium
fax [**]

With copy (which shall not constitute notice) to:
NOVASEP HOLDING SAS
Attn [**]
39 rue Saint Jean de Dieu
69007 Lyon, France
Fax [**]

For CUSTOMER: [**]
Freeline Therapeutics,
UCL Royal Free Medical School,
Pond Street, London,
NW3 2QG,
United Kingdom
Email [**]
Fax [**]

15.9 This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which shall be an original but all of which together shall constitute one and the same instrument. This Agreement is not effective until each Party has executed at least one (1) counterpart.

Made in two original copies, one for each Party.

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Signed by a duly authorized signatory for and on behalf of **HENOGEN SA**

Signature: [**]
Name: [**]
Position: Chief Executive Officer
Date: 11-Oct-2016

Signed by a duly authorized signatory for and on behalf of **FREELINE THERAPEUTICS LIMITED**

Signature: [**]
Name: [**]
Position: CEO
Date: 7-Oct-2016

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

**Part 3:
Work Plans**

[**]

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**Part 4:
Quality Agreement**

[**]

**Part 5:
Steering Group**

CUSTOMER Steering Group Members as at the Effective Date:

1. [**], Freeline Chief Development Officer (Chair)
2. [**], FIX Program Lead
3. [**], Freeline Chief Technology Officer

NOVASEP Steering Group Members as at the Effective Date:

1. [**], CEO of HENOGEN SA
2. [**], Strategic Project Director
3. [**], Strategy and Operations Director

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**Part 6:
Customer Pre-existing IP**

[**]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

**Part 7:
Novasep Pre-existing IP**

[**]

AMENDMENT

This amendment (the “**Amendment**”) enters into force at the date of signature by both parties (the “**Effective Date**”),

Between,

FREELINE THERAPEUTICS LIMITED, a company incorporated in England and Wales (Company No. 09500073) with registered office address at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, United Kingdom, hereafter referred as “**FREELINE**”,

and

HENOGEN SA, whose registered address is 12 rue des Professeurs Jeener et Brachet, B-6041 Gosselies, Belgium, hereafter referred as “**NOVASEP**”.

Given that **FREELINE** and **NOVASEP** have signed a service agreement (NPI012105-7) for Technology Transfer, Process Development and cGMP manufacturing of [**] dated October 11th 2016 and two amendments dated February 22nd 2018 (the “**Services Agreement**”).

Given that [**] a supplier of **NOVASEP** informed **FREELINE** and **NOVASEP** of an issue concerning the [**] pH sensor patches [**] and that said problem could not be resolved in the short run.

Given that pH control is a critical parameter for controlling **FREELINE**’s rAAV upstream process [**]

Given that **Freeline** have developed and demonstrated at full-scale a manual pH monitoring and controlling methodology based on off-line pH testing of samples, and that this was successfully implemented for the first GMP run at **NOVASEP**

Given the above and that **FREELINE** intends to keep the second clinical batch production scheduled in September 2018 (GMP run 02) (WP8.1)) and that a 3rd run (GMP run 03 (WP 8.3)) is booked for early 2019, the parties agree to amend the **Services Agreement** to address some additional resource costs and process risks arising from implementing this manual pH control methodology for future runs and known-reliability issues with the [**] and consumables

It is therefore agreed as follows:

1. **NOVASEP** will start the GMP run02 as scheduled with cell thawing on the 3rd of September 2018, applying manual pH control.

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2. Should the batch of Product fail to conform to the Specifications (as such terms is defined in the Services Agreement) and such failure be attributable to i) donut leakage (unless as a result of incorrect handling or operation) or ii) failure of the manual pH methodology (unless as a result of incorrect operation of this process), FREELINE shall pay NOVASEP [**] of such batch of Product as well as the cost of the Raw Materials (as such term is defined in the Services Agreement) which (i) were used during the production run, or (ii) were ordered by NOVASEP and could not be reallocated to another project. For the sake of clarity, it is agreed between the Parties that the number of sampling, included sampling for pH control, should not exceed five (5) samplings per day.

3. Since the manual pH control require additional resources (FTE) which were initially budgeted (including night shifts) and cause organisational change, FREELINE shall pay NOVASEP an additional [**] which includes the training of two additional operators, night shifts for the week (5) and night shifts for the weekend (2) for the GMP run 02 (WP8.1), and [**] for the GMP run 03 (WP8.3) which includes the training of one additional operator, and the night shifts. Such payment shall be made at the starting of each batch defined by cells thawing.

4. Except as otherwise specifically amended hereunder, all the other terms and provisions of the Services Agreement remain unchanged and shall continue to apply in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Services Agreement and any future reference to the Services Agreement shall include the terms and conditions of this Amendment.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment No. 3 to be executed by their duly authorized representatives.

Signed by a duly authorized signatory for and on behalf of **FREELINE THERAPEUTICS LTD**

Signature: [**]
Name: [**]
Position: CPO
Date: 2-Sep-2018

Signed by a duly authorized signatory for and on behalf of **HENOGEN SA**

Signature: [**]
Name: [**]
Position: CEO
Date: 7 Sept. 2018

This amendment (the “**Amendment**”) enters into force at the date of signature by both parties (the “**Effective Date**”),

Between,

FREELINE THERAPEUTICS LIMITED, a company incorporated in England and Wales (Company No. 09500073) with registered office address at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, SG1 2FX, United Kingdom, hereafter referred as “**FREELINE**”,

and

HENOGEN SA, whose registered address is 12 rue des Professeurs Jeener et Brachet, B-6041 Gosselies, Belgium, hereafter referred as “**NOVASEP**”.

Given that **FREELINE** and **NOVASEP** have signed a service agreement (NPI012105-7) for Technology Transfer, Process Development and cGMP manufacturing of [**] dated October 11th 2016 and an amendments #1 dated May 10th 2017 (the “**Services Agreement**”).

Given that **FREELINE** has requested **NOVASEP** to switch the third GMP batch [**] scheduled to start April 2020 [**]

Given that **NOVASEP** has performed a feasibility assessment of the switch and provided **FREELINE** with a report that highlights that the switch is feasible but that there are major risks associated with the use of a potentially non-conforming bioreactor (pH sensor) with automated control in USP and major modification of DSP process, and purchase of new articles and creation of documents represent a risk for proposed timelines.

It is therefore agreed as follows:

1. **NOVASEP** will start the GMP run03 as scheduled with cell thawing on the 13th of April 2020, applying automated pH control during [**] change notification **CN-RPII-B4PLXT [**]** The DSP process will be performed using a new process flowchart (Removal of the ILC step and addition of DMEM media, New TFF1).

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

2. Should the batch of Product fail to conform to the Specifications (as such terms is defined in the Services Agreement) and/or should be stopped before its completion and such failure be attributable to i) donut leakage (unless as a result of incorrect handling or operation) or ii) failure of the automated pH/ pH shift due to an uncorrect response of the pH Polestar patches or iii) a technical issue regarding the DSP process in its entirety (unless as a result of incorrect operation of this process), FREELINE shall pay NOVASEP [**] of such batch of Product as well as the cost of the Raw Materials (as such term is defined in the Services Agreement) which (i) were used during the production run, or (ii) were ordered by NOVASEP and could not be reallocated to another project. For the sake of clarity, it is agreed between the Parties that the number of sampling, included sampling for pH control, should not exceed two (2) samplings per day.

3. Since level sensors are defective, it requires additional resources (FTE) (night shifts), FREELINE shall pay NOVASEP [**] which includes the training of two additional operators, night shifts for the week (5) and night shifts for the weekend (2) for all the GMP run Such payment shall be made at the starting of each batch defined by cells thawing. People are on site and check in operational area during night and people act in 30-45min during weekend.

4. Except as otherwise specifically amended hereunder, all the other terms and provisions of the Services Agreement remain unchanged and shall continue to apply in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Services Agreement and any future reference to the Services Agreement shall include the terms and conditions of this Amendment.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment No. 3 to be executed by their duly authorized representatives.

Signed by a duly authorized signatory for and on behalf of **FREELINE THERAPEUTICS LTD**

Signature: [**]
Name: [**]
Position: SVP Product Supply
Date: 08 Apr 2020

Signed by a duly authorized signatory for and on behalf of **HENOGEN SA**

Signature: [**]
Name: [**]
Position: General Manager
Date: 09 Apr 2020

DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT

This **DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT** (this "Agreement"), effective as of this 6th day of October, 2017 (the "Effective Date"), between, **Freeline Therapeutics Limited** ("Customer"), having its principal place of business at 215 Euston Road, London NW1 2BE, UK, and **Brammer Bio MA, LLC**, a Delaware limited liability company with offices at 250 Binney Street, Cambridge, MA 02142 ("Brammer"). Customer and Brammer are referred to herein each as a "Party" and collectively as the "Parties".

WHEREAS, Brammer provides a full range of cell and gene therapy and viral vector process development and manufacturing services to the biopharmaceutical industry;

WHEREAS, Customer desires Brammer to perform certain services in accordance with the terms of and as more specifically set forth in this Agreement and its Work Statements (as defined below) related to the development, manufacture and supply of the Product (as defined below), and Brammer desires to perform such services;

WHEREAS, Customer and Brammer intend for this Agreement to cover certain development activities, including the transfer, facility fit and validation of Customer's Process (as defined below and attached hereto as Exhibit G), and the clinical supply and preparation for launch supply of the Product in accordance with the terms in Exhibit A;

WHEREAS, Customer and Brammer intend to enter into the first Work Statement ("Work Statement 1") on the same date as this Agreement, and, upon completion of the engineering run of the Product, to commence negotiations to finalize the second Work Statement, which will cover the clinical and preparation for launch supply of the Product: and

WHEREAS, Customer and Brammer further intend, subject to successful completion of Work Statement 1, to negotiate in good faith a Commercial Supply Agreement relating to the Product, substantially in the form set out in the non-binding Commercial Supply Term Sheet at Exhibit D.

NOW, THEREFORE, in consideration of the above statements and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto agree as follows:

1. **Definitions.** Terms defined elsewhere in this Agreement will have the meanings set forth therein for all purposes of this Agreement unless otherwise specified to the contrary. The following terms will have the meaning set forth below in this Section 1:

1.1 "Affiliate(s)" means any person, firm, trust, partnership, corporation, company or other entity or combination thereof which directly or indirectly: (a) controls a Party; (b) is controlled by a Party; or (c) is under common control with a Party. As used in this definition, the terms "control" and "controlled" will mean ownership of fifty percent (50%) or more (including ownership by trusts with substantially the same beneficial interests) of the voting and equity rights of such person, firm, trust, partnership, corporation, company or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof.

1.2 “Actual Expenditure” has the meaning set forth in Section 8.4.

1.3 “Applicable Laws” means all applicable ordinances, rules, regulations, laws, guidelines, guidances, requirements and court orders of any kind whatsoever of any Regulatory Authority applicable to a Party’s activities hereunder, as amended from time to time, including cGMP (if applicable) of the USA FDA, the EMA, the European Commission, the International Conference on Harmonization (ICH) guidelines and regulations, and other regulatory jurisdictions as agreed to by both Parties.

1.4 “Approval Date” means the date of receipt by Customer of the first regulatory approval to market the Product as Manufactured by Brammer.

1.5 “Approved Vendor(s)” has the meaning set forth in Section 5.1

1.6 “Assays” means the AUC and infectious titer assays.

1.7 “Assumptions” has the meaning set forth in Section 9.1

1.8 “Batch” means a specific quantity, as set out in a Work Statement, of Drug Substance or Drug Product that is intended to have uniform character and quality within specified limits and is produced according to a single cycle of Manufacture, and shall include, without limitation, pilot batches, engineering batches, and GMP batches.

1.9 “Batch Documentation” has the meaning set forth in Section 7.1.

1.10 “Batch Record” (also referred to as “Manufacturing Batch Record (MBR)” or “Batch Production Record (BPR)”) means a manufacturing record for a Batch generated by Brammer concurrently with the production of a specific Batch such that successive steps in such processes are documented, and includes without limitation all documentation necessary to maintain compliance, batch records, specifications, compliance and quality assurance documentation, Certificates of Analysis, certificates of compliance, manufacturing batch records, deviation reports (including operator error or equipment failure), packaging records, documentation or records of environmental monitoring, and other materials generated by Brammer during or in connection with the Batch, whether recorded in writing or electronically.

1.11 “Brammer IPR” has the meaning set forth in Section 12.4.

1.12 “Brammer Failure” [**]

1.13 “Brammer Materials” means the materials identified in the applicable Work Statement as being provided by Brammer to be used in the Manufacture of the Product under the applicable Work Statement, including Process Consumables.

1.14 “Brammer Parties” has the meaning set forth in Section 17.1.

1.15 "Brammer Technology" [**]

1.16 "Certificate of Analysis" means a written certificate listing the items tested, Manufacturer, specifications, testing methods and test results for a specific Batch.

1.17 "cGMP" or "GMP" means current good manufacturing practices, including the regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act, 21 C.F.R. Part 210 *et seq.*, as amended from time to time, applicable guidance documents issued by the FDA, EC Directive 2003/94/EC and European Medicines Agency guidance documents, applicable documents developed by the International Conference on Harmonization (ICH) to the extent that they are applicable to the Product and the Parties hereunder, and other Regulatory Authorities, as agreed to by the Parties, applicable to the manufacture and testing of pharmaceutical materials under Applicable Laws.

1.18 "Change of Control" means "any of the following events:

(i) any Third Party (or group of Third Parties acting in concert or otherwise) becomes the beneficial owner, directly or indirectly of, or otherwise obtains control, directly or indirectly of (A) a majority of the voting rights exercisable at shareholder meetings of a Party; or (B) the right to appoint or remove directors by holding a majority of the voting rights exercisable at meetings of the board of directors of the Party; or (C) the ability to direct or procure the direction of the management and policies of the Party, whether through ownership or shares, contract or otherwise; or

(ii) the Party consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into the Party, in either event pursuant to a transaction in which:

(1) the direct or indirect control of a majority of the voting rights exercisable at shareholder meetings of the surviving entity;

(2) the direct or indirect right to appoint or remove directors by holding a majority of the voting rights exercisable at meetings of the board of directors of the surviving entity; or

(3) the direct or indirect ability to direct or procure the direction of the management and policies of the surviving entity, whether through the ownership of shares; by contract or otherwise,

in each case is not held by the Persons holding such control, right or ability (as the case may be) preceding such consolidation or merger; or

(ii) the Party conveys, leases or transfers all or substantially all of its assets to any Third Party.

1.19 “Change Order” has the meaning set forth in Section 9.2.

1.20 “Claim” has the meaning set forth in Section 17.1.

1.21 “Commercially Reasonable Efforts” means, with respect to the activities of Brammer in the performance of the Services, carrying out such obligation using efforts consistent with contract development and manufacturing organizations in the biopharmaceutical industry, resources typically used by contract development and manufacturing organizations in the United States in the performance of such services to achieve a desired result, including human and technical resources, and the expenditure of funds which are necessary to complete such services and achieve such result. For clarity, acts of negligence or willful misconduct or failure to perform due to financial offers from third parties will not be deemed to be commercially reasonable.

1.22 “Confidential Information” means, all know-how (and all tangible and intangible embodiments thereof), and all other secret, confidential or proprietary information, data or materials, whether provided in written, oral, graphic, video, computer or other form, or by observation at the Party’s facilities, which is owned or controlled by a Party and is disclosed or made available by such Party or an Affiliate of such Party to the other Party or an Affiliate of such other Party pursuant to this Agreement which: (a) if disclosed in written, graphic, electronic or other tangible form, is labeled as confidential or proprietary, (b) if disclosed orally or visually, is identified as confidential or proprietary at the time of disclosure and is confirmed to be confidential or proprietary by the Disclosing Party in writing to the Receiving Party within thirty (30) calendar days of such disclosure, or (c) by its nature, should reasonably be considered to be confidential or proprietary. Confidential Information of Customer includes business, technical and financial data, and know-how concerning the Customer Provided Materials, Customer Technology and the Product, the Specification and the Process of Exhibit G, provided, however that, to the extent Brammer Technology or New Brammer Technology is included in the Product, Specification, or Process, such Brammer Technology and New Brammer Technology do not lose their status as Confidential Information of Brammer by virtue of having been incorporated therein; and Confidential Information of Brammer includes proprietary technical data, know-how, and trade secrets concerning Brammer’s production and purification methods, Brammer’s equipment and techniques, Brammer’s facilities and its design and operation, and Brammer Technology and New Brammer Technology, as well as business, financial and technical data.

1.23 “Customer Approval” has the meaning set forth in Section 7.1.

1.24 “Customer-Funded Equipment” means, if any, equipment which is funded and owned by the Customer, which may be used by Brammer solely in connection with the provision of the Services, and which will be installed, validated and maintained by Brammer during the term of this Agreement and will be specified in the applicable Work Statement.

1.25 “Customer Provided Materials” means the materials identified in the applicable Work Statement to be provided by Customer to Brammer hereunder, for use in the Manufacture of the Product under the applicable Work Statement. Customer Provided Materials will not include Brammer Materials.

1.26 “Customer Technology” [**] by or on behalf of Customer independent of this Agreement and without reliance upon the Confidential Information of Brammer.

- 1.27 “Customer Parties” has the meaning set forth in Section 17.2.
- 1.28 “Customer Representative” has the meaning set forth in Section 3.6.
- 1.29 “Defect” [**]
- 1.30 “Delinquency Period” has the meaning set forth in Section 8.5.
- 1.31 “Deliverable” means any work product to be provided by Brammer pursuant to this Agreement or a Work Statement, but excluding Product.
- 1.32 “Delivery Site” has the meaning set forth in Section 7.2.
- 1.33 “Disclosing Party” has the meaning set forth in Section 10.1.
- 1.34 “Disposition” means a documented decision on the acceptability for use of a specific Batch that is based on a process of reviewing data associated with the production and testing of the product.
- 1.35 “Drug Product” means the Product Manufactured by Brammer on behalf of Customer, into its final container closure, whether or not labeled.
- 1.36 “Drug Substance” means the non-sterile active pharmaceutical ingredient (as defined by ICH Q7) Manufactured by Brammer on behalf of Customer and identified in the applicable Work Statement.
- 1.37 “EMA” means the European Medicines Agency, and any successor agency entity thereof having or performing substantially the same function.
- 1.38 “Estimate” has the meaning set forth in Section 8.3.
- 1.39 “EU” means all of the European Union member states as of the applicable time during the term of this Agreement.
- 1.40 “Existing Confidentiality Agreement” means that certain Confidential Disclosure Agreement, dated 17th January 2017 by and between the Parties.
- 1.41 “Facility” means the Brammer manufacturing, laboratory and warehouse facility specified in the applicable Work Statement, or any other Brammer facility as agreed to in writing by the Parties.
- 1.42 “Force Majeure Event” has the meaning set forth in Section 21.

- 1.43 “FDA” means the United States Food and Drug Administration or any successor entity thereof having or performing substantially the same function.
- 1.44 “FTE” has the meaning set forth in Section 12.5(i).
- 1.45 “General Assumptions” has the meaning set forth in Section 9.1.
- 1.46 “ICH” means the International Conference on Harmonization.
- 1.47 “Improvement” means any modification, enhancement or improvement to a Technology, or any discovery related to such Technology, whether or not patented or patentable, and all associated Intellectual Property Rights therein or thereto.
- 1.48 “Indemnified Party” has the meaning set forth in Section 17.3.
- 1.49 “Indemnifying Party” has the meaning set forth in Section 17.3.
- 1.50 “Intellectual Property Rights” means any and all of the following: (a) Patents, (b) copyrights in both published and unpublished works, (c) rights in trade secrets and know-how, whether or not patentable or copyrightable, (d) trademark and service mark rights, (e) any and all other intellectual property rights, and (f) any and all registrations and applications for registration of any of the foregoing.
- 1.51 “Latent Defect” [**]
- 1.52 “Losses” has the meaning set forth in Section 17.1.
- 1.53 “Manufacture,” “Manufactured,” and “Manufacturing” means the steps, processes and activities used by Brammer to produce the Product, including, for example, the manufacturing, processing, packaging, labeling, testing, stability testing, Process Performance Qualification, and the release, shipping, storage or supply of Product as provided in the Work Statement, Batch Record and Master Batch Record.
- 1.54 “Master Batch Record” means the document containing the Specifications and instructions for the Manufacture and quality assurance of a Product, as such may be amended by the Parties in accordance with the terms hereof.
- 1.55 “Materials” means Customer Provided Materials and Brammer Materials.
- 1.56 “MHRA” means the Medicines and Healthcare products Regulatory Agency of the United Kingdom (“UK”).
- 1.57 “New Brammer Technology” [**]
- 1.58 “New Customer Technology” [**]

1.59 “New Technology” means the New Brammer Technology or the New Customer Technology, as applicable.

1.60 “Pass-Through Costs” has the meaning set forth in Section 8.2.

1.61 “Patents” means patents and patent applications issued or pending therefrom anywhere in the world, together with any and all divisions, renewals, continuations and continuations-in-part thereof, and all patents granted thereon, and all reissues, re-examination certificates, certificates of invention and applications for certificates of invention, revalidations, substitutions, supplementary protection certificates, additions, utility models, and term restorations, extensions and foreign counterparts thereof.

1.62 “Permitted Recipients” has the meaning set forth in Section 8.2.

1.63 “Person” means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust or joint venture, or a governmental agency or political subdivision thereof.

1.64 “Process” means the processes and procedures used to Manufacture a Product in accordance with the Master Batch Record, including all protocols and standard operating procedure documents referenced therein, which are provided by Customer to Brammer or developed by Brammer and Customer hereunder.

1.65 “Process Consumables” means media, raw materials, chromatography columns, resins, filters, membranes, disposable analytical test kits, hoses, fitter housings, tubing, filling needles, disposable bags, disposable glass/plastic ware, cleaning supplies and other changeover parts used during the Manufacture of Product. Parties may list other Process Consumables to be added to the scope of this Agreement in subsequent Work Statements.

1.66 “Process Performance Qualification” or “PPQ” means the process agreed by the Parties for the collection and evaluation of data, from the process design stage through repeated production at final scale, which establishes scientific evidence that a Manufacturing Process is capable of consistently and reproducibly delivering Product meeting Specifications.

1.67 “Product” means Customer’s product defined in the applicable Work Statement.

1.68 “Program” means all of the Services to be performed by Brammer for Customer as described in Work Statement(s) for such Program, including any properly mutually agreed and authorized amendments or Change Orders thereto.

1.69 “Program Assumptions” has the meaning set forth in Section 9.1.

1.70 “Program Manager” has the meaning set forth in Section 3.6.

1.71 “Quality Agreement” has the meaning set forth in Section 3.7.

1.72 “Receiving Party” has the meaning set forth in Section 10.1.

1.73 “Regulatory Authority” means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the manufacture, production, use or storage or transport, of any Product, including the FDA, the EMA, the MHRA and the European Commission.

1.74 “Reprocess” means introducing a Product back into, and repeating appropriate manipulation steps that are part of, the established Process.

1.75 “Result(s)” means all in-process analytical results, materials, data obtained, and reports developed and/or generated by Brammer in performing the Services related to the Product or Process. Any results, materials or data obtained, developed or generated outside of the conduct of the Services or that are not related to the Product or Process will not constitute Results. For the avoidance of doubt, documents that may be generated or used in the course of performing Services under the Program, but that are general to Brammer’s business and do not relate to the Product or Process, such as a Facility and equipment SOPs, will not constitute Results.

1.76 “Retained Copies” has the meaning set forth in Section 20.5(ii).

1.77 “Retention Period” has the meaning set forth in Section 11.2.

1.78 “Service Fee” has the meaning set forth in Section 8.1.

1.79 “Services” means the services and activities to be performed by Brammer, any Brammer Affiliate, any of their respective employees, agents or consultants, or Approved Vendors hereunder as part of a Program, as more specifically set forth in the applicable Work Statement.

1.80 “SOP” means the written standard operating procedures and methods of Brammer, as the same may be amended, in Brammer’s sole discretion, from time to time.

1.81 “Special Waste” means waste or effluent, which is required to be collected in a special container for external disposal.

1.82 “Specifications” means, with respect to a particular Product, the list of tests, references to any analytical methods and appropriate acceptance criteria which are numerical limits, ranges or other criteria for tests described, which establishes a set of criteria to which such Product should conform to be considered acceptable for its intended use, in each case, as in effect from time to time. The Parties will agree to the Specifications through the performance of the Services under the Work Statements.

1.83 “Stage” means a stage of the Program as set out in the applicable Work Statement.

1.84 “Technology” means all scientific, technical and other information, data, know-how, trade secrets, inventions (whether or not patentable), processes, compositions of matter, materials, methods, techniques, documentation, hardware, software and technology, whether or not protected or protectable under patent, trademark, copyright or similar law.

1.85 “Third Party” means any party other than Customer, Brammer and their respective Affiliates.

1.86 “Travel Expenses” means costs and expenses incurred by Brammer for travel and lodging required in order to carry out any Program.

1.87 “Wait Period“ has the meaning set forth in Section 12.7.

1.88 “Work Statement“ means a detailed work order, substantially in the form attached hereto as Exhibit A, that (a) includes, as appropriate, a description that specifies the Program, the scope of the Services under such Program, the estimated duration of the Program, and all other matters pertinent to completion of the Program, (b) references this Agreement, (c) is signed by authorized representatives of both Parties and (d) sets forth, at a minimum, the Services to be provided by Brammer and the fees to be paid by Customer for such Services, including the anticipated Travel Expenses, if any, and any modifications to such work statement that the Parties may agree in writing from time to time.

2. Work Statements.

2.1 This Agreement contains general terms and conditions under which Customer may engage Brammer to provide, and Brammer would provide, Services. Customer and Brammer will complete and execute an initial Work Statement as Exhibit A before any Services are provided. Each Work Statement will include, as appropriate, a description that specifies the Program, the scope of the Services under such Program, the estimated duration of the Program, and all other matters pertinent to completion of the Program, and, once executed by both Parties, such Work Statement will be deemed a part of this Agreement and incorporated herein by reference. To the extent any terms or provisions of a Work Statement conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement will control, except to the extent that the applicable Work Statement expressly states an intent to modify the terms of this Agreement on a specific matter. The Parties may amend a Work Statement by agreement in writing from time to time during the term of this Agreement.

2.2 The Parties envisage that they will enter into two Work Statement(s) in connection with this Agreement, with the second Work Statement covering Part 2 of the program of work, as set out in outline in Work Statement 1. In consideration of the Customer agreeing to commence good faith negotiations for the second Work Statement with Brammer no later than the date on which the engineering run Batch of the Product is accepted by the Customer, [**]

2.3 A Program will be complete when all Stages of the applicable Work Statement(s) have been completed or when the applicable Work Statement or this Agreement has been terminated pursuant to Section 20.

2.4 With respect to each Work Statement, Customer acknowledges that Brammer consulted with Customer in developing the Work Statement in a manner consistent with Brammer’s then current reasonable understanding of, as applicable, United States (the “U.S.”), EU and UK, and other regions as agreed to by the Parties, regulatory guidelines to the extent applicable to the Product and the Parties. Brammer does not, however, represent or warrant that the Program and/or the Results of the Services will satisfy the requirements of any Regulatory Authorities at the time of submission of such Results to such Regulatory Authorities. Customer will be responsible for obtaining all regulatory approvals relating to registration of the Product, but not for any existing licenses of Brammer, and will own the applicable regulatory filings and approvals. As between the Parties, Customer will be responsible for complying with all Applicable Laws relating to the shipping, distribution and marketing of Product.

3. **Program Performance.**

3.1 Brammer will use Commercially Reasonable Efforts to perform the Services for Customer in accordance with the applicable Work Statement and in accordance with all Applicable Laws.

3.2 [**]

3.3 Brammer will comply with cGMP applicable to the Services, provided that, should cGMP applicable to the Services be changed following the Effective Date, Brammer will use Commercially Reasonable Efforts to comply with such new cGMP requirements without interruption to cGMP status. In the event that compliance with such new cGMP requirements necessitates, in the reasonable determination of the Parties, a change in the Work Statement or the Services, Brammer will submit to Customer a proposed Change Order in accordance with Section 9.2.

3.4 Customer acknowledges that due to the unpredictable nature of biological processes, a Process Performance Qualification (as envisaged to be completed in the second Work Statement) needs to have taken place to establish the commercial process of Manufacturing the Product.

3.5 Brammer undertakes that it shall:

- (i) use Commercially Reasonable Efforts to ensure that the Facility is ready to perform for the first relevant activity under each Work Statement in accordance with the timeline mutually agreed to by the Parties for such activity; Customer acknowledges that the timelines set forth in any Work Statement are good faith estimates using assumptions based on information available on the date on which the applicable Work Statement is executed. Customer understands that it needs to comply in a timely manner with all of its relevant obligations in order to enable Brammer to achieve such timelines;
- (ii) give the Customer prompt written notice of any anticipated delay in the completion of the Facility; and
- (iii) in the event of any delay in the Facility being ready in accordance with (i), use its best efforts (a) to complete the commissioning of the Facility as soon as possible and (b) to perform its obligations under each Work Statement using alternative resources and Facilities, including by giving the Customer priority in the use of available Brammer capacity.

3.6 Brammer will appoint a Brammer representative (the "Program Manager") to be responsible for overseeing the conduct of the Services and the completion of the Program by Brammer. The Program Manager will coordinate performance of the Services with a representative designated by Customer in writing (the "Customer Representative"), which representative will have responsibility over all matters relating to performance of the Services on behalf of Customer. Unless otherwise agreed in the Work Statement, or mutually agreed to by the Parties, all communications between Brammer and the Customer regarding the conduct of the Services pursuant to the Work Statement will be addressed to or

routed through the Program Manager and Customer Representative. The Program Manager and the Customer Representative are named in the Work Statement, and Brammer or Customer may, at its option, substitute, respectively, the Program Manager or the Customer Representative during the course of the Program by providing written notice to the other.

3.7 The Program Manager shall co-ordinate meetings of a joint project team to oversee and co-ordinate the performance of this Agreement on a day-to-day basis. The Program Manager and the Customer Representative shall determine, acting reasonably, which other individuals should be part of the joint project team or otherwise attend joint project team meetings from time to time. The joint project team shall meet in person or by phone every two (2) weeks, or more frequently as may be agreed. The Program Manager shall be responsible for taking minutes of each meeting of the joint project team and circulating such minutes to the Customer Representative for review.

3.8 The Parties shall each nominate two (2) individuals to sit on a joint steering committee to oversee the performance of this Agreement (the "JSC"). The JSC shall meet, whether in person or by telephone, once every 6 months, or ad hoc as may be agreed, to review the progress of all Work Statements and any other matters relating to the Agreement, based on written reports provided to them by the Program Manager and the Customer Representative. Where the JSC is unable, in good faith, to reach agreement on any matter referred to them, either Party may refer the matter for dispute resolution under Section 16. The matters referred to the JSC shall include, without limitation, the agreement of a Specification for a Work Statement; disputes over whether a Product contains a Defect; and such other matters as the Parties may determine from time to time.

3.9 Promptly following the execution of this Agreement, the Parties will enter into a detailed document specifying the quality and regulatory procedures and responsibilities of the Parties with respect to the Manufacture of Product (the "Quality Agreement", substantially in the form of the draft annexed as Exhibit E; provided, however, that, upon execution, the executed Quality Agreement will replace the draft in Exhibit E). In the event of any conflict between the terms and provisions of this Agreement and the terms and provisions of the Quality Agreement, the terms of this Agreement will control, except with respect to quality related matters.

3.10 The Parties confirm that, subject to successful completion of Work Statement 1, they intend to negotiate in good faith a Commercial Supply Agreement relating to the Product, substantially in the form set out in the non-binding Commercial Supply Term Sheet at Exhibit D.

4. **Program Materials.**

4.1 **Customer Provided Materials.**

(i) Customer will provide Brammer with sufficient amounts of the Customer Provided Materials with which to perform the Services as specified in the Work Statement. Unless the Work Statement includes the development of a manufacturing process by Brammer, Customer also will provide Brammer with all necessary Confidential information in Customer's possession and control to effect the reliable transfer of the Process from Customer to Brammer.

(ii) Customer Provided Materials will be delivered by Customer to the Facility at no cost to Brammer. Unless otherwise agreed by the Parties, Customer will deliver the Customer Provided Material in quantities sufficient to meet the expected requirements of Product Manufacturing.

(iii) Customer will provide Material Safety Data Sheets for all Customer Provided Materials and for each Product that are, in each case, accurate and complete to the best of

Customer's knowledge having taken all appropriate steps to inform itself of the same. Customer will notify Brammer of any unusual adverse health or environmental occurrence relating the Customer Provided Materials, and any Product, including but not limited to any claim or complaint by any Customer employee or Third Party.

(iv) Customer Provided Materials will remain the sole property of Customer at all times during the term of this Agreement, but will remain in the possession, control and care of Brammer following delivery of such Customer Provided Materials by Customer to the Facility. Brammer will use and store the Customer Provided Materials with due care and in compliance with Customer's instructions as set forth in the applicable Work Statement. Title and risk of loss or damage to such Materials will at all times remain with Customer, and Brammer will have no liability to Customer for such Materials except due to Brammer's negligence, breach of this Agreement or failure to comply with Applicable Laws.

(v) Import, Export, Customs. For all Customer Provided Materials being delivered to Brammer for Customer's account, and all Materials delivered by Brammer for Customer's account, Customer will be responsible at its sole cost and expense for satisfying all import, export and customs requirements, including United States Export Control Regulations, and Customer will be the importer and exporter of record (or utilize its own customs broker) for any Customer Provided Materials being imported and shipped to Brammer and for all Materials exported to another country, in each case, for Customer's account (but excluding, for the avoidance of doubt, any Materials exported by Brammer to an Affiliate or Third Party in connection with the performance of the Services, and any corresponding import). Brammer shall provide Customer with reasonable assistance in relation to the import and export of Materials pursuant to this Agreement, and Customer's obligations as the importer and exporter of record of all materials.

(vi) Upon completion of the Program, any remaining Customer Provided Materials will be, at Customer's sole expense and election (such election to be made by Customer to Brammer in writing no later than [**] either after Brammer's issuance of a Certificate of Analysis for the last applicable Product, or receipt of a notice of termination), returned to the Customer or destroyed/disposed of by Brammer. If Customer does not provide such election to Brammer within such [**] Brammer will, at Customer's expense, return to the Customer the applicable Customer Provided Materials. Notwithstanding anything to the contrary contained in this Agreement, (i) Brammer may retain Customer Provided Materials as required by Applicable Laws, and (ii) in no event will Brammer be required to store Customer Provided Materials for more than [**] after termination or expiration of an applicable Work Statement or this Agreement unless the Parties have entered into an appropriate storage agreement covering such items.

4.2 Brammer Materials and equipment; Customer-Funded Equipment.

(i) Brammer will use Commercially Reasonable Efforts to procure the Brammer Materials and all required equipment in a timely manner for use in the Program and each Manufacturing run as set forth in the Work Statement. Brammer will qualify vendors, perform audits according to agreed procedures and test and release Materials according to agreed procedures prior to the start of Manufacturing.

(ii) If necessary, Brammer will procure Customer-Funded Equipment to the extent required to perform the Service. Any required Customer-Funded Equipment and associated expenses will be set forth in the applicable Work Statement.

5. **Use of Vendors.**

5.1 Brammer reserves the right to employ vendors from time-to-time to undertake certain Services related to a Program (for example, for specialty testing, waste disposal, etc.) upon prior written notice to Customer describing the activities to be performed. All vendors must be pre-approved in writing by the Customer (“Approved Vendors”). A list of existing Approved Vendors as of its execution will be included in the Work Statement and updated from time to time, and any fees payable to an Approved Vendor must be approved in advance in writing by Customer. For mutually agreed upon non-routine Services provided by Approved Vendors (e.g., Services that are developmental in nature or specific to a Product and not, for example, standard specialty testing and waste disposal Services), each such Approved Vendor will be bound by written confidentiality, nonuse, and quality assurance obligations consistent with this Agreement, as well as an assignment to Brammer of all inventions or other intellectual property arising in the course of performing such Services, as necessary for Brammer to comply with its obligations to Customer under this Agreement.

5.2 Subject to the foregoing, Brammer will be responsible to Customer for managing the performance of Approved Vendors used for the Program. Brammer will work together with the Approved Vendor, and Customer if appropriate, to resolve any issues or failures by the Approved Vendor. Brammer shall only be responsible for the actions (or inactions) of an Approved Vendor resulting in a failure or Defect if such failure or Defect is the result of a Brammer Failure, in which case such failure or Defect shall be addressed in accordance with Section 7.9 and 7.10. Brammer will use Commercially Reasonable Efforts to enforce its legal and contractual rights (which, for non-routine Services and pursuant to Section 5.1, shall be in writing) against such Approved Vendor as necessary for Brammer to comply with its obligations under this Agreement or upon request from the Customer in the event of a material breach by such Approved Vendor.

6. **Facility Audits and Facility Visits.**

6.1 Facility Audits. Subject to Brammer’s safety procedures, access control SOPs, and confidentiality limitations, Brammer will permit Customer’s representatives, not more frequently than [**], during the term of this Agreement at mutually agreed upon times to audit the Facility as more specifically set forth in the Quality Agreement, provided, however, that Customer may conduct any additional for-cause audits at mutually agreed upon times with reasonable advance notification to Brammer. Customer will give Brammer reasonable advanced notice of any proposed routine audit but no fewer than [**] prior notice for a for-cause audit, and identify the individuals who will be in attendance; **provided that** a general quality audit will require a minimum of [**] prior notice. All routine audits will be during Brammer’s normal business hours on weekdays and conducted in a manner that does not unreasonably interfere with Brammer’s Services and does not otherwise unreasonably interfere with normal business activities. Brammer will [**] make its Facilities and all relevant records available for inspection by representatives of Regulatory Authorities in compliance with Applicable Laws, [**] All information, records, or business information concerning Brammer that is disclosed or made available by Brammer to Customer employees and representatives, and representatives of Regulatory Authorities, or otherwise obtained by such employees and representatives, in connection with any audit will be deemed to be Confidential Information of Brammer. [**]

6.2 Facility Visits. Subject to Brammer's safety procedures, access control SOPs, and confidentiality limitations, Brammer will permit Customer's representatives during the term of this Agreement, to visit the Facility at mutually agreed upon times, to support technology transfer and/or observe procedures and processes at mutually agreed upon times with reasonable advance notification to Brammer. Customer will give Brammer reasonable advanced notice of any proposed visit, but no fewer than [**] prior notice, and identify the individuals who will be in attendance, provided however that [**] notice will be required where Customer's representatives wish to visit the Facility in connection with a for-cause audit or an urgent Product safety related matter. All visits will be during Brammer's normal business hours on weekdays and conducted in a manner that does not unreasonably interfere with Brammer's Services and does not otherwise unreasonably interfere with normal business activities.

7. Delivery and Acceptance Procedures.

7.1 Delivery and Acceptance of Batch Documentation. Brammer will manufacture each Batch of Product in accordance with the applicable Specifications and the relevant Work Statement, and store each such Batch in accordance with the applicable provisions of the Quality Agreement. As soon as Brammer has determined that such Batch complies with the Specifications and is ready for release to Customer, Brammer will send by fax and/or e-mail to Customer: (a) a packing list if applicable, (b) an invoice, (c) the Batch Record, and (d) the Certificate of Analysis (collectively, the "Batch Documentation"). Upon Customer's written acceptance of the Batch Documentation (or [**] following delivery to Customer of the Batch Documentation, if Customer makes no response) ("Customer Approval"), the Batch Documentation will be deemed approved and the relevant Batch of Product will be delivered as provided in Section 7.2.

7.2 Delivery of Batch. Following Customer Approval (pursuant to Section 7.1) of the Batch Documentation, Brammer will deliver each Batch of Product to Customer Ex Works (Incoterms 2010) to the Facility (the "Delivery Site") and Customer will take delivery of the same. Title to each Batch of Product will pass to Customer when Customer or Customer's designated carrier takes delivery of such Batch at the Delivery Site, and any undisputed invoices relating to the Batch are paid. All risks of loss or damage to any Batch of Product will pass to Customer on delivery at the Delivery Site. Brammer shall, without charge, provide Customer with reasonable support and advice in connection with the export of Product from the Delivery Site.

7.3 Acceptance of Batch Procedures. Upon receipt of each Batch of the Product, Customer will:

(i) inspect the Product and confirm that the quantity of Product received by Customer matches the quantity of Product set forth in the Batch Documentation, and make all the necessary reserves on the delivery receipt related to any shortage in the quantity of Product;

(ii) inform Brammer, by email of any shortage identified through the conduct of the inspection pursuant to Section 7.3(i) within [**] from the date of receipt by Customer of such Batch of Product; and

(iii) inform Brammer by email of any Defect within [**] from the date of delivery of such Batch of Product at the Delivery Site. Following receipt of such email Brammer and Customer will immediately initiate an investigation to determine the cause of the Defect.

7.4 Where any shortage in the quantity of Product received by the Customer is identified, the Customer may, in its sole discretion, either:

- (i) accept the quantity of Product delivered and require Brammer not to deliver the shortfall amount; or
- (ii) require Brammer to deliver the shortfall amount promptly and in any event within thirty (30) days.

Where the Customer chooses (i) above, the Customer is only obliged to pay for the volume of Product actually delivered.

7.5 During the period of [**] referred to in 7.3(iii) above, Customer shall be entitled to inspect and accept or reject such Batch for: (a) non-conformance with the Specifications; and (b) other non-conformance or shortage, based on an inspection of the visible appearance of such Batch. Customer will be under no obligation to accept a Batch with a Defect until the cause of the Defect has been determined, such cause to be investigated by Customer and Brammer in a timely manner.

7.6 In the event of any suspected Latent Defect notified to Brammer [**] the Parties shall work together to investigate the nature and cause of the Defect. The Customer shall either destroy or return to Brammer the defective Product and make no use of it. The Customer agrees that it shall not use any Product in any clinical trial (i) until the Customer has received notice from Brammer that Product has been released by Brammer QA; or (ii) if Brammer QA has at any time following such release of Product subsequently requested suspension of clinical use of the Product.

7.7 Acceptance of Deliverables. Where Brammer is required pursuant to a Work Statement to provide certain Deliverables, the Customer shall [**] to review them, including the ability to comment upon a draft version of any reports, and inform Brammer of any defect or issue in connection with such Deliverables, and to reject or accept such Deliverables. If no notice of rejection or acceptance is provided by Customer [**] Customer will be deemed to have accepted such Deliverables and the applicable invoice will be payable.

7.8 Disputes. In case of any disagreement between the Parties as to whether Product contains a Defect or a Latent Defect, whether a Deliverable is defective, or the existence of a Brammer Failure, the Customer Representative and the Program Manager will attempt in good faith to resolve any such disagreement and each Party will follow its standard operating procedures to determine whether such Product contains a Defect or Latent Defect and/or the cause of any such Defect or Latent Defect (or, as appropriate, whether the Deliverable is defective). If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed [**] from the date of the provision of notice regarding such Defect, Latent Defect or non-delivery or defective Deliverables) then discussion will be escalated to the JSC for resolution. In the event that the JSC is unable to resolve the matter within [**], the Parties shall refer the matter (of whether a Product contains a Defect or a Latent Defect, or whether a Deliverable is defective, or the existence of a Brammer Failure) for determination by an appropriately qualified independent laboratory, the identity of which will be agreed by the Parties in good faith, [**] The Parties agree that the determination of the independent laboratory shall be final and binding.

7.9 Drug Substance Non-Compliance and Remedies. Subject to Sections 7.11 and 7.13, if a Batch of Drug Substance contains a Defect caused by a Brammer Failure as determined upon investigation, Brammer will at Customer's election:

- (i) [**]

[**]

7.10 Drug Product Non-Compliance and Remedies. Subject to Sections 7.11 and 7.13, if a Batch of Drug Product contains a Defect caused by a Brammer Failure as determined by an investigation, Brammer will at Customer's election:

(i) [**]

[**]

7.11 Other Defects. Notwithstanding anything to the contrary in this Agreement, Brammer will not have any liability for or responsibility to replace or Reprocess any Product which is defective or fails, or ceases to conform to the Specifications, or which is unusable for its intended purposes, in each case, unless such defect results from a Defect in Product which is not accepted under Section 7.3 and was caused by a Brammer Failure, or is a Latent Defect. Without limiting the generality of the foregoing, Brammer will not have any liability for or responsibility to replace or Reprocess any Product which is defective or fails or ceases to conform to the Specifications or which is unusable for its intended purposes, in each case, for any other reason.

7.12 Disposition of Non-Conforming Product. The ultimate disposition of non-conforming Product will, at Brammer's cost only for Brammer Failure, be the responsibility of Customer's quality assurance department.

7.13 Exclusive Remedy. The sole and exclusive remedies available to Customer for a Brammer Failure in connection with a Batch Defect or otherwise in connection with Product which fails or ceases to conform to the Specifications due to a Brammer Failure will be the remedies set forth in Section 7.9 or Section 7.10.

8. Compensation.

8.1 Customer will pay Brammer the fees and other payments and costs listed in the applicable Work Statement (the "Service Fees"), subject to Section 9. Brammer will issue invoices for Service Fees in accordance with the payment schedule set forth in the Work Statement, and Customer will pay the amounts set forth in each invoice within [**] of the date of such invoice, unless Customer notifies Brammer in writing of a disputed invoice amount. In the case of a disputed amount, the Parties will in good faith discuss the item and seek resolution and Customer will pay all undisputed amounts, if any, of such invoice.

8.2 The Service Fees do not include amounts payable by Customer for (a) Process Consumables; (b) Customer-Funded Equipment; (c) Services subcontracted to an Approved Vendor (including shipping charges for delivery of materials to and from an Approved Vendor); or (d) collection, storage, handling, transportation and disposal of Special Waste; ((a) through (d), collectively, "Pass-Through Costs"). Subject to Section 8.4 below, Brammer will invoice Customer for all Pass-Through Costs as incurred by Brammer. Amounts payable for Customer-Funded Equipment will include the direct cost to acquire the equipment, which will be procured and invoiced in accordance with Exhibit B. [**]

8.3 In the case of Process Consumables for the remainder of the Work Statement, at completion of Stage 1 of the Work Statement, and, in the case of Services subcontracted to an Approved Vendor, prior to the initiation of each Stage of the Program, Brammer will prepare and provide to Customer a good-faith itemized estimate (an "Estimate") of expected costs and expenses to be incurred by Brammer for Process Consumables and Services subcontracted to an Approved Vendor for such Stage. Within five (5) business days of receipt of each Estimate, Customer will either notify Brammer of Customer's acceptance and agreement of such Estimate, or notify Brammer with reasonable detail of any disputed items set forth in the Estimate. Failure to so notify Brammer within such five (5) business day period will be deemed to be Customer's agreement and acceptance of such Estimate. If Customer disputes any items set forth in the Estimate within such five (5) business day period, the Parties will discuss in good faith the disputed items and Brammer will re-issue an Estimate to Customer and the review and acceptance process set forth above will be applied to such re-issued Estimate. Following approval of each Estimate, Brammer will proceed, in accordance with the time schedule set forth in the Work Statement, with the purchase of Process Consumables.

8.4 Brammer will invoice Customer for such Process Consumables and Pass-Through Costs for the same amount included in the relevant approved Estimate. Upon completion of the applicable Stage or earlier termination of this Agreement, or the applicable Work Statement, Brammer will calculate the expenditure actually incurred for Process Consumables up to the date of completion or termination, plus the administrative fee as outlined in Section 8.2, and for the Customer-Funded Equipment procured for use during such Stage and associated costs (collectively, the "Actual Expenditure"). If the Actual Expenditure is greater than the corresponding Estimate, Brammer will issue a further invoice for a sum equivalent to the difference between the amount set forth in the Estimate and actually paid by Customer and the Actual Expenditure, subject always to any cap on Actual Expenditure which is included in the relevant Work Statement. If the Actual Expenditure is less than the corresponding Estimate, Brammer will issue a credit note against the earlier invoice for a sum equivalent to the difference, which credit may be applied to future amounts payable under this Agreement. Customer will pay the amounts set forth in each invoice within [**] of the date of such invoice, unless Customer notifies Brammer in writing of a disputed invoice amount. In the case of a dispute under this Section 8.4, the Parties will in good faith discuss the item and seek resolution and Customer will pay all undisputed amounts, if any, of the relevant invoice.

[**]

8.5 Late payments of undisputed amounts under this Agreement will incur an interest charge of [**] Brammer reserves the right to suspend the Services in the event of late payments of undisputed amounts after providing Customer written notice of such late payments and allowing Customer a period of [**] to pay the late amounts (any time after such period, the “Delinquency Period”), Brammer reserves the right to refuse receipt of new Customer Provided Material for Manufacture of additional Batches of Product and to otherwise suspend the Services.

8.6 All payments under this Agreement are exclusive of any taxes that may apply and will be paid gross, without deductions or set-offs, whether by way of withholding or other income taxes, and Customer will ensure that such sum is paid to Brammer as will, after deduction of such withholding or other income taxes, be equivalent to the consideration payable under this Agreement. Any duty, sales, use or excise taxes imposed by any governmental entity that apply to the provision of the Services will be borne by Customer (other than taxes based upon the income of Brammer).

8.7 All amounts payable to Brammer under this Agreement will be paid in U.S. Dollars, without deduction, and by authenticated and value dated Swift telegraphic transfer for any such payments made from outside the U.S., quoting invoice numbers of payment to the bank account identified in the applicable invoice or by such other means as Brammer will notify Customer in writing from time to time.

9. **Work Statement and Specifications Changes.**

9.1 The Service Fees are subject to a number of specific and general assumptions. The specific assumptions relate to the Work Statement and Program design and objectives, timing, capital expenditure requirements, if any, and other assumptions relating to the completion of the Program as set forth in the Work Statement (the “Program Assumptions”). Brammer also assumes that the Customer will cooperate and perform its obligations under the Agreement in a timely manner, that no event outside the reasonable control of Brammer will occur, including the events described in Section 21 and that there are no changes to any Applicable Laws that materially adversely affect the Program (collectively, the “General Assumptions,” and together with the Program Assumptions, collectively, the “Assumptions”). In the event that any of the Assumptions require modification or the objectives of the Program cannot be achieved based on the Assumptions then the Work Statement may be amended as provided in Section 9.2.

9.2 In the event Brammer is requested or required to perform services beyond that which are set forth in a Work Statement, any such additional services and compensation schedule must be mutually agreed upon by the Parties in writing prior to the provision of said services (a “Change Order”). A sample Change Order is attached hereto as Exhibit C. Each Change Order will detail the requested changes to the applicable task, responsibility, duty, budget, time line or other matter. A Change Order will become effective upon the execution of a Change Order by both Parties, and a Change Order will specify the period of time within which Brammer must implement the changes. Both parties agree to act in good faith and promptly when considering a Change Order requested by the other Party.

10. **Confidential Information/Legal Proceedings/Publicity.**

10.1 **Term of Confidentiality Obligations.** Except as otherwise provided in this Section 10, during the term of this Agreement and for a [**] of this Agreement, each Party (the “Receiving Party”) agrees that it will keep the other Party’s (the “Disclosing Party’s”) Confidential Information confidential and use it solely to conduct the activities contemplated, and to exercise rights, under this Agreement, and for no other purpose. The foregoing notwithstanding, with respect to Confidential Information that constitutes a trade secret, the Receiving Party’s obligations under this Agreement to keep such information confidential will continue for as long as such information remains a trade secret.

10.2 **Confidentiality and Non-Use Obligations.** Each Party agrees that all Confidential Information disclosed to such Party or any of such Party’s Affiliates by the other Party or an Affiliate of such other Party (a) will not be used by the Permitted Recipients except as authorized under this Agreement and in connection with the activities contemplated by this Agreement or in order to further the purposes of this Agreement and (b) will be maintained in confidence by the Receiving Party and such Party’s Affiliates, with a degree of care that is not less than the Receiving Party typically exercises with respect to its own most valuable Confidential Information and in any case with not less than reasonable care. The Receiving Party will provide, upon the Disclosing Party’s request, a certification that access and use is being controlled in accordance with this Agreement. The Disclosing Party will have the right to audit to verify compliance with this Agreement. Notwithstanding any other provision of this Agreement, disclosure of Confidential Information will not be prohibited to the extent required to comply with Applicable Laws or regulations, or with a valid court or administrative order, **provided that** the Receiving Party will (i) notify the Disclosing Party of any such disclosure requirement or request as soon as practicable (and to the extent that it is legally able to do so); (ii) cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party’s cost) if the Disclosing Party seeks a protective order or other remedy in respect of any such disclosure; and (iii) furnish only that portion of the Confidential Information which is responsive to such requirement or request. If Brammer becomes obliged to provide testimony or records regarding this Agreement in any legal or administrative proceeding relating to Customer, Customer will reimburse Brammer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Brammer’s standard commercial rates.

10.3 **Disclosures to Permitted Recipients.** Each Party agrees that such Party and such Party’s Affiliates will provide Confidential Information received from the Disclosing Party only on a need-to-know in connection with this Agreement basis and only to the Receiving Party’s respective employees, directors, consultants, advisors, bona fide potential partners or investors, and to the employees, directors, consultants and advisors of the Receiving Party’s Affiliates (collectively, “Permitted Recipients”), solely under conditions of confidentiality and non-use at least as stringent as the conditions imposed by this Agreement, and **provided that** each Party will remain responsible for any failure by its Permitted Recipients to treat such information and materials as required under Section 10.2. Neither Party shall allow access to the Confidential Information of the other Party to any Permitted Recipient who does not require such access in order to accomplish the purposes of this Agreement. Receiving Party and its Affiliates will use at least the same standard of care as it uses to protect its own most valuable confidential information and in any case with not less than reasonable care, to ensure that its Permitted Recipients do not disclose or make any unauthorized use or disclosure of the Confidential Information.

10.4 **Exceptions to Confidential Information.** Confidential Information will not include information that:

(a) was known or used by the Receiving Party or such Party’s Affiliates prior to its date of disclosure to the Receiving Party as demonstrated by appropriate evidence; or

(b) either before or after the date of the disclosure to the Receiving Party or the Receiving Party's Affiliate is lawfully disclosed to the Receiving Party or any of such Party's Affiliates by sources other than the Disclosing Party rightfully in possession of such know-how and not bound by confidentiality obligations to the Disclosing Party; or

(c) either before or after the date of the disclosure to the Receiving Party or any of such Party's Affiliates is or becomes published or otherwise is or becomes part of the public knowledge, through no breach hereof on the part of the Receiving Party or such Party's Affiliates; or

(d) is independently developed by or for the Receiving Party or any of such Party's Affiliates without reference to or reliance upon the Confidential Information of the Disclosing Party as demonstrated by appropriate convincing evidence.

Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

10.5 Responsibility for Compliance with Confidentiality and Nonuse Obligations.

(i) The Receiving Party will be responsible for any intentional misuse or misappropriation by the Receiving Party or its Affiliates, or the Permitted Recipients or sublicensees of the Receiving Party or its Affiliates, of the Disclosing Party's Confidential Information.

(ii) Customer will promptly notify Brammer in writing of the Customer becoming aware of any actual or threatened disclosure, misappropriation or other violation of Brammer's Confidential Information by a Third Party, Customer, or Customer's Affiliate.

(iii) Cooperation. If at any time the Disclosing Party brings, or investigates the possibility of bringing, any claim against any Person for misappropriation of trade secrets and misuse of Confidential Information, then the Receiving Party, upon the request and at the expense of the Disclosing Party, will cooperate with and assist the Disclosing Party in the investigation or pursuit of such claim, and provide the Disclosing Party with any information in the possession of the Receiving Party that may be of use to the Disclosing Party in the investigation or pursuit of such claim.

10.6 Disclosure of Provisions of Agreement.

(i) Each Party agrees to hold as confidential the terms of this Agreement, except that (a) each Party shall have the right to disclose such terms to investors, bona fide potential investors, business partners, bona fide potential business partners, lenders, bona fide potential lenders, acquirers, bona fide potential acquirers, and investment bankers in connection with licensing, financing and acquisition activities, and due diligence processes related to such activities, **provided that** (a) any such Third Party has entered into a written obligation with the disclosing Party to treat such information and materials as confidential and requiring at least commercially reasonable obligations of confidentiality (and each Party will remain responsible for any failure by any of the foregoing Persons, to whom a Receiving Party may disclose Confidential Information) to treat such information as required under Section 10.2 hereof, and (b) each Party will have the right to disclose such terms as required by Applicable Law, regulation or legal

process, including by the rules or regulations of the SEC or similar regulatory agency in a country other than the United States, or of any stock exchange or other securities trading institution; **provided that** the Party subject to such disclosure requirement will, if reasonably practicable under the circumstances, provide the other Party with a reasonable opportunity to review and comment in advance on the disclosing Party's proposed disclosure and such disclosing Party will consider in good faith any comments thereon provided by the other Party. Such Party will exercise at least a reasonable standard of care and take commercially reasonable steps to protect Confidential Information of the Disclosing Party and disclose only such portion of Confidential Information of the Disclosing Party, if at all, as is reasonably required to be disclosed.

(ii) In the event that this Agreement will be included in any report, statement or other document filed by Customer or an Affiliate of Customer with the SEC or similar regulatory agency in a country other than the United States or any stock exchange or other securities trading institution, Customer will use, or will cause such Customer's Affiliate, as the case may be, to use, good faith efforts to obtain confidential treatment from the SEC, similar regulatory agency, stock exchange or other securities trading institution of any Brammer proprietary technical data, know-how, and trade secrets concerning Brammer's production and purification methods, Brammer's equipment and techniques, Brammer's facilities and its design and operation, and Brammer Technology and New Brammer Technology, as well as financial information or other information of a competitive or confidential nature, and will include in such confidentiality request such provisions of this Agreement as may be reasonably requested by Brammer.

10.7 Remedies. The Receiving Party acknowledges that a breach by it of any of the terms of this Agreement would cause irreparable harm to the Disclosing Party for which the Disclosing Party could not be adequately compensated by money damages. Accordingly, the Receiving Party agrees that, in addition to all other remedies available to the Disclosing Party in an action at law, in the event of any breach or threatened breach by the Receiving Party of the terms of this Agreement, the Disclosing Party will, without the necessity of proving actual damages or posting any bond or other security, be entitled to seek temporary and permanent injunctive relief, including, but not limited to, specific performance of the terms of this Agreement.

10.8 Non-Solicitation and Non-Hire. From the Effective Date [**] no Party will solicit an employee of another Party who is or has been involved in any activity to which this Agreement pertains. Notwithstanding the foregoing, nothing herein will restrict or preclude each Party's rights to make generalized searches for employees by way of a general solicitation for employment placed in a trade journal, newspaper or website, and which is not designed to target or specifically attract the employees of the other Parties.

10.9 No Disclosure of Unrelated Information. Neither Party will disclose confidential information to the other Party that is not reasonably necessary for performance of a Party's obligations under this Agreement, including but not limited to manufacturing processes for other products, marketing plans and clinical development plans. Notwithstanding the foregoing, nothing in this provision will limit the confidentiality and non-use obligations and rights herein.

10.10 Customer Provided Materials. Brammer will not transfer any Customer Provided Materials to any Third Party without Customer's written permission, unless such transfer is to an Approved Vendor, is consistent with the Program and is for use only for activities set out in the relevant Work Statement

10.11 No Licenses. Except as expressly provided in Section 12 hereof, no right or license, either express or implied, is granted under any Intellectual Property Right or by virtue of the disclosure of Confidential Information under this Agreement, or otherwise. The Parties agree that each Party has and will retain sole and exclusive rights of ownership in and to any Confidential Information of such Party.

10.12 Acknowledgment or Prior Confidentiality Obligations. The Parties acknowledge that Confidential Information has been provided by the Parties to each other prior to the Effective Date of this Agreement pursuant to the Existing Confidentiality Agreement. All Confidential Information (as defined in the Existing Confidentiality Agreement) exchanged between the Parties under the Existing Confidentiality Agreement will be deemed Confidential Information under this Agreement and will be subject to the terms of this Agreement.

11. **Work Product; Records**.

11.1 All work outputs, including reports of Results, will be prepared in accordance with Brammer's standard format unless otherwise specified in the Work Statement.

11.2 For each Batch of Product and any other Services provided, Brammer will keep and maintain records, including all Results produced in the conduct of the Services, for a period of [**] after completion of a Deliverable, or such longer period as required by the Applicable Laws (the "Retention Period"). For clarity, Brammer will be entitled to retain all original documents relating to the Program and will provide to Customer an electronic and paper copy of all Batch Records and other reports provided under this Agreement. At the end of the Retention Period, such records shall, at Customer's option and expense, either be (i) delivered to Customer or to its designee, or (ii) disposed of, but only after giving Customer [**] prior written notice of Brammer's intent to do so.

11.3 Brammer will take and retain, for such period and in such quantities as may be required by cGMP (if applicable) and the applicable Quality Agreement, samples of Product Manufactured under this Agreement, including samples required by Customer ("Customer-Owned Retains"). Further, upon Customer's written request and to the extent consistent with cGMP and Applicable Law, Brammer will provide to Customer reasonable access to such Customer-Owned Retains or agree that Brammer will perform testing on the Customer-Owned Retains. [**]

11.4 Right of Cross-Reference. [**] Brammer shall deliver to Customer for filing with the FDA or any foreign Regulatory Authority designated by Customer such authorization letters as Customer deems necessary for the foregoing purpose, which shall be in substantially the form attached hereto as Exhibit E, subject to such modifications as may be required by Applicable Law; *provided, however*, that if Customer proposes any material modifications to such form, Brammer shall be entitled to [**] for review and approval of the modified form; and *provided, further*, that Customer shall be responsible for all costs and expenses associated with its request for such cross-reference, and for obtaining any notarization, legalization or apostille that may be required for filing any authorization letter with any foreign Regulatory Authority. For the avoidance of doubt, Brammer shall not be required to provide directly to Customer any Brammer documents that are general to Brammer's business, such as a Facility and equipment SOPs unless such documents are expressly requested by a relevant Regulatory Authority or are required by Applicable Law.

12. Intellectual Property

12.1 Customer Technology. All right, title and interest in and to Customer Technology will remain vested solely in Customer. Customer hereby grants Brammer a non-exclusive, royalty-free license under all Intellectual Property Rights relating to Customer Technology for the sole purpose of performing the Services on behalf of Customer. Such license will expire upon the completion of such Services or the termination or expiration of this Agreement, whichever is the first to occur. Customer agrees that:

(i) Upon Brammer's prior written request, and in accordance with instructions provided by Brammer, Customer will, at Customer's expense and in its sole discretion, transfer such embodiments of Customer Technology as are reasonably required for the performance of the Services to Brammer for the sole purpose of enabling Brammer to perform the Services.

(ii) Without limiting the generality of the foregoing, Customer will provide to Brammer without charge, such written materials and assistance of Customer personnel as may be reasonably requested by Brammer to assist with the transfer and use of Customer Technology in performing the Services. All information provided to Brammer under this Section will be subject to the confidentiality provisions of this Agreement.

12.2 Brammer Technology. As between the Parties, all right, title and interest in and to Brammer Technology and all Intellectual Property Rights therein will remain solely in Brammer, except as provided in Section 12.4.

12.3 New Technology. In the event that, during performance of the Services, Brammer (or any personnel or entity acting on behalf of Brammer, including Approved Vendors retained to perform non-routine Services consistent with Section 5.1 and the Work Statement) solely or jointly with Customer creates, conceives, develops, or reduces to practice new Technology ("New Technology"), whether or not patentable, the following will apply:

(i) New Customer Technology. Customer will hold all right, title and interest in and to all New Customer Technology and all Intellectual Property Rights therein. Brammer hereby assigns, and to the extent not presently assignable shall assign, to Customer all right, title, and interest in and to all New Customer Technology. Brammer will take, and will procure that all Approved Vendors, retained to perform non-routine Services consistent with Section 5.1 and the Work Statement, shall take any actions, including but not limited to the execution of documents, reasonably requested by Customer, and at Customer's expense, to effect such assignment. Customer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any Patent that claims or covers the New Customer Technology.

(ii) New Brammer Technology. Brammer will hold all right, title and interest in and to all New Brammer Technology and all Intellectual Property Rights therein. Customer hereby assigns, and to the extent not presently assignable shall assign, to Brammer all right, title, and interest in and to all New Brammer Technology. Customer will take any actions, including but not limited to the execution of documents, reasonably requested by Brammer, and at Brammer's expense, to effect such assignment. Brammer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any Patent that claims or covers the New Brammer Technology.

12.4 License to Customer. [**]

12.5 Technology Transfer to Customer. [**]

12.6 Customer acknowledges that Brammer is in the business of providing services for a variety of organizations other than Customer. Accordingly, nothing in this Agreement or any Work Statement hereunder will preclude or limit Brammer from utilizing the general knowledge gained during the course of its performance hereunder to perform similar services for other customers.

12.7 The Parties acknowledge that successful completion of the Services may require a license under Third Party Intellectual Property Rights. [**] In the event either Party is put on notice by a Third Party of alleged infringement by Brammer of Third Party Intellectual Property Rights due to the Manufacture of Product, such Party will promptly inform the other Party of such notification. [**] Brammer will not be responsible for any adverse impact on the quality and stability of the process intermediates or final Product during the Wait Period or any subsequent impact on the process intermediates of final Product to the extent such impact is caused by the Wait Period, provided however that Brammer will keep Customer promptly informed of any such potential impact, and will discuss in good faith with Customer the extension of the Wait Period where such an extension is reasonably required to prevent damage to the Product or any intermediaries.

12.8 Brammer reserves the right to utilize data generated during the course of Services to support applications, assignments or other instruments necessary to apply for and obtain Patents with respect to Brammer Technology and New Brammer Technology, provided the data so utilized is de-identified and does not contain Customer Confidential Information. Brammer will notify Customer in advance of filing for any such Patent and Customer will have the right to require Brammer to reasonably delay any such Patent filing if such filing contains data that is Customer Confidential Information or which may be the subject of a Patent filing with respect to any New Customer Technology.

13. **Independent Contractor.** Brammer will perform the Services as an independent contractor of Customer and will have complete and exclusive control over the Facility, the equipment, and its employees and agents. Nothing in this Agreement will constitute Brammer, or anyone furnished or used by Brammer in the performance of the Services, as an employee, joint venturer, partner, or servant of Customer. Brammer also agrees that it will not have any rights to receive any employee benefits such as health insurance and accident insurance, sick leave or vacation as are in effect generally for employees of Customer. Neither Party will enter into any agreements or incur obligations on behalf of the other Party, nor commit the other party in any other manner without prior written consent from a duly authorized officer or representative of such other Party.

14. **Insurance.**

14.1 Customer will obtain and maintain with insurers having A.M. Best ratings of A-VII or higher at all time as of and after the Effective Date of this Agreement, at its own expense, [**]. Customer agrees to maintain at all times thereafter during the term of this Agreement such appropriate Clinical Trial Limits. Customer will provide Brammer with reasonable evidence of such coverage within thirty (30) days of execution of this Agreement. If any such policy is replaced, Customer agrees to purchase tail coverage or ensure that the new policy has a retroactive date that is consistent with the start of any work under a Work Statement and that Customer will continue to be covered on the replacement policy. Customer will provide Brammer with at least thirty (30) days' prior written notice of any change in or cancellation of the insurance coverage.

15. **Shipping.** Brammer will package for shipment Product, samples or other materials in accordance with the Work Statement and Customer's written instructions and at the Customer's expense. All shipments will be in accordance with Section 7.1 and Customer will bear all packaging, shipping and insurance charges. Brammer will pass through actual shipping and related charges as set forth in the Work Statement.

16. **Dispute Resolution.**

16.1 In the event any dispute arises between the Customer and Brammer with respect to any of the terms and conditions of this Agreement or the Program that cannot be resolved by the Customer

Representative and the Brammer Program Manager, then senior executives of the Customer and Brammer will meet as promptly as practicable after notice of such dispute to resolve in good faith such dispute. The senior executives of the Parties will attempt in good faith to resolve such dispute by negotiation and consultation for a thirty (30) day period following such referral.

16.2 If the Senior Executives of Customer and Brammer are unable to satisfactorily resolve the dispute within thirty (30) days, then such dispute will be finally settled by arbitration in accordance with this Section 16.2. The arbitration will be held in New York, NY, and except as noted below, will be conducted in accordance with the rules of the American Arbitration Association (or such successor organization) by one mutually agreeable arbitrator, who will be a lawyer having at least fifteen years of experience dealing with complex contracts, including those in biologics manufacturing. If the Parties cannot agree on an arbitrator within a reasonable period of time, an arbitrator will be appointed by the American Arbitration Association (or such successor organization). The arbitrator will have no authority to vary from or ignore the terms of this Agreement and will be bound by controlling law. The Parties may seek judicial intervention for emergency relief, such as restraining orders and injunctions where appropriate.

16.3 Any decision by the arbitrator will be binding upon the Parties and may be entered as final judgment in any court having jurisdiction. The cost of any arbitration proceeding will be borne by the Parties as the arbitrator will determine if the Parties have not otherwise agreed. The arbitrator will render his or her final decision in writing to the Parties.

16.4 The dispute resolution of Section 16 is without prejudice to the rights of the Parties to obtain injunctive relief under Section 10.7.

17. **Indemnification.**

17.1 Customer will indemnify and hold harmless Brammer and its Affiliates and each of its directors, officers, employees, and agents (the "Brammer Parties") against any and all Third Party charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands ("Claims") imposed upon a Brammer Party and associated damages awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations and expenses, including reasonable attorneys' fees) (collectively, "Losses") suffered or incurred in consequence of the following:

[**]

17.2 Brammer will indemnify and hold harmless Customer and its Affiliates and each of its directors, officers, employees, and agents (the “Customer Parties”) against any and all Third Party Claims and associated Losses that the Customer Parties suffered or incurred in consequence of the following:

[**]

17.3 Upon receipt of notice of any Claim that may give rise to a right of indemnity from the other Party hereto, the Party seeking indemnification (the “Indemnified Party”) will give prompt written notice thereof to the other Party, (the “Indemnifying Party”) of the Claim for indemnity. Such Claim for indemnity will indicate the nature of the Claim and the basis therefor. Promptly after a claim is made for which the Indemnified Party seeks indemnity, the Indemnified Party will permit the Indemnifying Party, at its option and expense, to assume the complete defense of such Claim, provided, that, (a) the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense; (b) the Indemnifying Party will conduct the defense of any such Claim with due regard for the business interests and potential related liabilities of the Indemnified Party; and (c) the Indemnifying Party will, prior to making any settlement, consult with the Indemnified Party as to the terms of such settlement. The Indemnifying Party will not, in defense of any such Claim, settle or consent to an adverse judgment in any such claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnified Party or imposes additional material obligations (financial or otherwise) on such Indemnified Party, without the prior express written consent of such Indemnified Party (such consent not to be unreasonably withheld, conditioned or delayed). After notice to the Indemnified Party of the Indemnifying Party’s election to assume the defense of such Claim, the Indemnifying Party will only be liable to the Indemnified Party for such reasonable legal or other expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnifying Party will be liable for all reasonable legal or other expenses incurred by the Indemnified Party in connection with the defense thereof and the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such

defense at the Indemnifying Party's own cost and expense, and will not settle or otherwise dispose of any of the same without the consent of the Indemnifying Party (such consent not to be unreasonably withheld, conditioned or delayed.) If requested by the Indemnifying Party, the Indemnified Party agrees to cooperate with the Indemnifying Party and its counsel in contesting any Third Party Claim which the Indemnifying Party defends, or, if (i) appropriate and related to the Third Party Claim in question and (ii) reasonable in the judgment of the Indemnifying Party, in making any counterclaim against the Person asserting the Third Party Claim, or any cross complaint against any Person. If Brammer will be obliged to provide testimony or records regarding the subject matter of this Agreement in any legal or administrative proceeding not covered by the indemnity set forth above, Customer will reimburse Brammer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Brammer's standard commercial rates. If Customer will be obliged to provide testimony or records regarding the subject matter of this Agreement in any legal or administrative proceeding pursuant to any general inspection of Brammer's Facility or operations, Brammer will reimburse Customer for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at cost.

18. **Limitations of Liability.**

18.1 BRAMMER'S LIABILITY UNDER THIS AGREEMENT HOWSOEVER ARISING WILL NOT EXCEED [**] BRAMMER ASSUMES NO LIABILITY FOR USE, STORAGE (AFTER TITLE PASSES TO CUSTOMER), DISPOSAL, MARKETING, OR SALE OF PRODUCT(S).

18.2 Consequential Damages Waiver. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, BUT NOT LIMITED TO, DAMAGES BASED UPON LOST PROFITS, BUSINESS INTERRUPTION, LOST BUSINESS, OR LOST SAVINGS (EXCEPT THAT IN CASE OF BREACH BY CUSTOMER, BRAMMER CAN RECOVER ITS LOST PROFITS UNDER THIS AGREEMENT THAT BRAMMER LOST AS A RESULT OF THE CONTRACT NOT BEING FULLY PERFORMED)) FOR ANY ACTS OR FAILURE TO ACT UNDER THIS AGREEMENT, EVEN IF IT HAS BEEN ADVISED OF THEIR POSSIBLE EXISTENCE.

18.3 The limitations of liability reflect the allocation of risk between the Parties. The limitations specified in this Section 18 will survive and apply even if any limited remedy specified in this Agreement is found to have failed of its essential purpose.

19. **Representations, Warranties and Covenants.**

19.1 Brammer Representations, Warranties and Covenants. Brammer represents, warrants and covenants to Customer that:

- (i) it has the full power and right to enter into this Agreement and that, to its knowledge, there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by any Affiliate or any Third Party, private or public, that are inconsistent with the provisions of this Agreement;
- (ii) the execution and delivery of this Agreement by Brammer has been authorized by all requisite corporate or company action and this Agreement is and will remain a valid and binding obligation of Brammer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

[**]

(iv) Brammer, its Affiliates and its Approved Vendors: (i) have not been debarred and are not subject to a pending debarment pursuant to Section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)); (iii) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. Brammer will notify Customer immediately if Brammer or any of its Affiliates or Approved Vendors is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Brammer's knowledge, is threatened; and

[**]

[**]

19.2 Customer Representations and Warranties. Customer represents, warrants and covenants to Brammer that:

(i) it has the full power and right to enter into this Agreement and that there are, to its knowledge, no outstanding agreements, assignments, licenses, encumbrances or rights held by any Affiliate or Third Party, private or public, that are inconsistent with the provisions of this Agreement;

(ii) the execution and delivery of this Agreement by Customer has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Customer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(iii) the Customer Provided Materials will be provided to Brammer free and clear of all liens and encumbrances and will be prepared by Customer in accordance with the agreed-upon specifications in the Work Statement;

(iv) [**]

(v) [**]

(vi) to the best of Customer's knowledge, the Customer Provided Materials are safe and non-hazardous for purposes of the Services to be performed hereunder.

19.3 EXCEPT AS SET FORTH HEREIN, BRAMMER EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED BY STATUTE, CUSTOM OF THE TRADE OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTIES OF TITLE OR NONINFRINGEMENT. ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ANY PERSON OR ENTITY ON BEHALF OF BRAMMER, INCLUDING EMPLOYEES OR REPRESENTATIVES OF BRAMMER, THAT ARE INCONSISTENT HERewith, WILL BE DISREGARDED AND WILL NOT BE BINDING ON BRAMMER. TO THE EXTENT PERMITTED BY APPLICABLE LAW, BRAMMER ASSUMES NO LIABILITY FOR USE, STORAGE (AFTER TITLE PASSES TO CUSTOMER), DISPOSAL, MARKETING, OR SALE OF PRODUCT(S).

20. **Term; Termination; Certain Effects of Termination.**

20.1 Unless earlier terminated in accordance with this Section 20, this Agreement will commence on the Effective Date and will continue until all Work Statements have been completed or terminated.

20.2 Mutual Agreement. [**]

20.3 Termination by Customer.

(i) **Termination of Clinical Trials.** [**] [**] [**]

(ii) **Termination for Convenience.** [**] [**] [**] Stage basis:

(iii) [**]

20.4 Termination by Either Party.

(i) **Termination for Material Breach. [**]**

[**]

(ii) **Termination by Insolvency.** [**]

(iii) [**]

(iv) In the event that Customer terminates this Agreement or any Work Statement pursuant to Section 20.4(i) (Termination for Brammer's Material Breach):

[**]

(v) In the event that Customer terminates this Agreement or any Work Statement pursuant to Section 20.4(ii) (Termination by insolvency):

[**]

20.5 In case of expiration or termination of this Agreement or any Work Statement for any reason, the following will apply:

- (i) Brammer will, as soon as possible, supply Customer with documentation concerning the Results obtained through the effective date of expiration or termination upon satisfaction of amounts due.
- (ii) Each Party will promptly return to the other all data and documents in any form comprising or containing any Confidential Information of the other Party, *except that* the Receiving Party may retain: (i) one copy of Confidential Information in secure legal archives for evidentiary purposes only and (ii) a copy of computer records or files containing such Confidential Information that have been created pursuant to automatic archiving or back-up procedures that cannot reasonably be deleted (collectively, "Retained Copies"), **provided, however, that** any such Retained Copies will be kept confidential by the Receiving Party in accordance with the terms and provisions of this Agreement for as long as the Receiving Party is in possession of the Retained Copies.
- (iii) Brammer will deliver to Customer at the Delivery Site any and all quantities of Product Manufactured up to the effective date of expiration or termination upon satisfaction of amounts due and Customer will take delivery of the same, except that Brammer may [**].
- (v) Brammer will return all Customer-Funded Equipment to Customer promptly on the termination or expiry of this Agreement or, where such Customer-Funded Equipment is not required for a subsequent Work Statement, any relevant Work Statement.
- (vi) Brammer will return, ship, or destroy Customer Provided Materials and Brammer Materials procured according to the Work Statement at the Customer's direction and sole expense (other than in the case of termination for Brammer's Material Breach, in which case such costs shall be borne by Brammer), including expenses relating to shipping costs, return fees to vendors and any unreimbursed costs on any non-refundable or non-returnable items; **provided that** Brammer may dispose of Customer Provided Materials in its discretion, and Customer will have no right to the same, in the event Brammer does not receive direction in accordance with this Section 20.5 within [**] of termination or expiration of the relevant Work Statement.

20.6 With the termination of this Agreement, all Work Statements shall terminate, unless otherwise agreed to by the Parties. The termination of any individual Work Statement will have no effect on the continued existence and enforceability of this Agreement or any other Work Statement then pending. The expiry or termination of one Work Statement does not terminate another active Work Statement or this Agreement. Except the expiry of the Term of this Agreement, the Agreement is deemed to continue and apply to any outstanding Work Statement until the expiry or earlier termination of that Work Statement.

20.7 The termination of this Agreement for any reason will not affect any accrued rights or obligations of either Party as of the effective date of such termination, including obligations in respect of compensation for Services performed prior to the effective date of such expiration or termination of this Agreement. The following provisions will survive any expiration or termination of this Agreement: Sections 8, 10 through 12 (inclusive), 14, and 16 through 31 (inclusive), the provisions of the applicable Quality Agreement, and any other provision in this Agreement or its exhibits and attachments that by its nature and intent should remain valid after the expiration or termination of the Agreement.

21. **Force Majeure.** Either Party will be excused from performing its respective obligations under this Agreement, except for any obligation to make payment under a validly issued invoice, if its performance is delayed or prevented by any event beyond such Party's reasonable control (each, a "Force Majeure Event"), including acts of God, fire, explosion, weather, disease, war, terrorism, insurrection, civil strife, riots, labor dispute or strike, government action, or a shortage or failure of power outside such Party's reasonable control, **provided that** such performance will be excused only to the extent of and during such disability and **provided that** financial inability in and of itself will not be a Force Majeure Event. Any time specified for completion of performance in the Work Statement falling due during or subsequent to the occurrence of any or such events will be automatically extended for a period of time reasonably necessary to recover from such disability, provided however that the Parties shall, within [**] of the start of such delay, discuss the delay and how best to resolve the matter. Where Brammer is unable to complete performance within [**] of the start of any delay caused by a Force Majeure Event, Customer shall be entitled to terminate this Agreement and any Work Statement on [**]. Customer shall also have the right to terminate this Agreement and any Work Statement on [**] notice where Brammer's performance is delayed through Force Majeure Events by more than [**] in total in any calendar year. Brammer will promptly notify Customer if, by reason of any of the events referred to herein, Brammer is unable to meet any such time for performance specified in the Work Statement.

22. **Publicity.** Customer will not make a press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement, or any ancillary matter, without first obtaining the prior written consent of Brammer. Customer will provide a copy of the proposed text thereof to Brammer for its review and approval at least ten (10) days prior to the proposed release. Brammer may provide specific, reasonable comments on such release, announcement or publicity reasonably in advance of the date of the proposed release, but will not unreasonably withhold or delay its approval to such release, announcement or publicity. Brammer will not make a press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement without Customer's prior written consent.

23. **Assignment.** This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement (a) in connection with the transfer or sale of all or substantially all of the assets of such Party to which this Agreement relates or, in the case of Customer, the Product; (b) in the event of the merger, reorganization or consolidation of a Party; or (c) to any Affiliate. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume all obligations of its assignor under this Agreement, provided however that if either Party assigns this Agreement to an Affiliate, such Party will continue to remain obligated under this Agreement; and, further provided, that, in connection with any assignment to a Third Party described in this Section 23, (i) the assigning Party will provide the other Party with prompt written notice of assignment, (ii) the permitted assignee will assume in writing all obligations of its assignor under this Agreement.

24. **No Implied Licenses.** No right or license under any Brammer Technology, New Brammer Technology, and Process of either Party is granted or will be granted by implication. All such rights or licenses are or will be granted only as expressly provided in this Agreement.

25. **Press Releases.** The Parties agree that any initial public announcement of the execution of this Agreement will be in the form of a mutual press release to be agreed upon by the Parties; provided, that the Parties will also agree on the timing of such public announcement. After such press release is published, each Party will be entitled to make or publish any public statement consistent with the contents thereof. Except as set forth in the preceding sentence, no press release, publicity or other form of public written disclosure related to this Agreement will be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing. This Section 25 will not apply to any disclosure that is deemed necessary, in the reasonable judgment of the responsible Party, to comply with national, federal or state laws or regulations.

26. **Use of Names.** Neither Party will make use of the name of the other Party in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party.

27. **Notices.** All notices to be given as required in the Agreement will be in writing and may be delivered by email or delivered personally or mailed either by a reputable overnight carrier with required receipt signature or certified mail, postage prepaid to the Parties at the addresses set forth below or at such other address as either Party may provide by written notice to the other party in accordance with the provisions of this Section 27. Such notice will be effective: (a) on the date sent, if delivered personally or by email (receipt of which is confirmed); (b) the date after delivery if sent by overnight carrier; or (c) on the date received if sent by certified mail.

If to Customer:

Freeline Therapeutics Limited
Attn: [**] Chief Development Officer
[**]
Email: [**]

If to Brammer:

Brammer Bio MA, LLC
Attn: [**] President & CEO
[**]
Email: [**]

28. **Choice of Law.** This Agreement, and all matters arising directly or indirectly hereunder, will be governed by, and construed in accordance with the laws of the State of New York, without giving effect to its choice of law provisions. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980.

29. **Waiver/ Severability.** No waiver of any provision of this Agreement, whether by conduct or otherwise, in any one or more instances will be deemed to be or be construed as a further or continuing waiver of any such provision, or of any other provision or condition of this Agreement. The invalidity of any portion of this Agreement will not affect the validity, force or effect of the remaining portions of this Agreement. If it is ever held that any provision hereunder is too broad to permit enforcement of such provision to its fullest extent, such provision will be enforced to the maximum extent permitted by law.

30. **Entire Agreement; Modification/Counterparts.** This Agreement, together with the Work Statements and Appendices attached hereto, sets forth the entire agreement between the Parties hereto with respect to the performance of the Program by Brammer for Customer and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, and commitments with respect thereto and will take precedence over all terms, conditions and provisions of any purchase order form or form of order acknowledgment or other document purporting to address the same subject matter. This Agreement will not be waived, released, discharged, changed or modified in any manner except by an instrument signed by the duly authorized officers of each of the Parties hereto, which instrument will make specific reference to this Agreement and will express the plan or intention to modify same. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. For purposes of execution, facsimile signatures will be deemed originals.

31. **Construction.** Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The headings and captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein will mean including, without limiting the generality of any description preceding such term. The language of this Agreement will be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Signature Page Follows]

Certain confidential information contained in this document, marked by [**], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

BRAMMER BIO MA, LLC

By: [**]
Name: [**]
Title: PRESIDENT & CEO

FREELINE THERAPEUTICS LIMITED

By: [**]
Name: [**]
Title: CEO

NONEXCLUSIVE LICENSE AGREEMENT
FACTOR IX VECTOR PRODUCTION TECHNOLOGY

THIS AGREEMENT is entered into as of **24 March 2017** (the “Effective Date”) by and between St. Jude Children’s Research Hospital, a Tennessee not for profit corporation having a place of business at 262 Danny Thomas Place, Memphis, Tennessee 38105 (hereinafter “St. Jude”) and Freeline Therapeutics Limited, a limited liability company having a place of business at 215 Euston Road, London NW1 2BE (hereinafter “Licensee”).

WITNESSETH THAT:

WHEREAS, St. Jude is the owner of Patent Rights and FIX Know-How as later defined herein; and

WHEREAS, St. Jude wishes to have the Patent Rights and FIX Know-How further developed and marketed at the earliest possible time in order that products resulting therefrom may be available for public use and benefit; and

WHEREAS, Licensee wishes to enter into an agreement to obtain a license to the Patent Rights and FIX Know-How from St. Jude in order to practice the invention claimed therein and to make, use and sell in the commercial market the products made in accordance therewith; and

WHEREAS, St. Jude is willing to grant such a license to Licensee under the terms and conditions set forth in this Agreement.

NOW, THEREFORE, St. Jude and Licensee hereby agree as follows:

ARTICLE I - DEFINITIONS

1.01. “AAV Product” shall mean an adeno-associated viral vector the manufacture of which uses **FIX** Know-How and/or would, were it not for this Agreement, infringe at least one Valid Claim of Patent Rights.

1.02. “Affiliate” shall mean any legal entity that controls, is controlled by, or is placed under the same control as Licensee. For the purposes of this definition, the term “control” means beneficial ownership of at least fifty percent (50%) of the voting or income interest of a legal entity.

1.03. “Confidential Information” shall mean any confidential or proprietary information furnished by one party (the “Disclosing Party”) to the other party (the “Receiving Party”) in connection with this Agreement.

1.04. “FIX Product” shall mean an AAV Product specifically designed for delivering Factor IX to patients.

1.05. “Intellectual Property” shall mean patents, trademarks, service marks, registered designs, copyrights, database rights, design rights, confidential information (whether registered or unregistered), applications for any of the above, and any similar right recognised from time to time in any jurisdiction, together with all rights of action in relation to the infringement of any of the above

1.06. “Know-How” shall mean unpatented technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, data, designs, formulae, ideas, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications whether contained or not in submissions to regulatory authorities, quality control data, analyses, reports and submissions) that is not in the public domain.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

1.07. "FIX Know-How" shall mean the [**]

1.08. "Net Sales" shall mean [**]

1.09. "Patent Rights" shall mean the [**] the inventions described therein, and any divisional, continuation, or continuation-in-part and foreign counterparts of such patent application to the extent that the claims are directed to subject matter disclosed therein, as well as any U.S. or foreign patents issued thereon and any reissue or extension of such patents, all to the extent that such patents have not expired and have not been determined to be invalid or unenforceable by a decision of a court from which no appeal can be taken.

1.10. "Sub-Licensee" shall mean any third party to whom commercial rights are granted by Licensee in relation to an AAV product for which Licensee holds the right to commercialize.

1.11. "Transfer Documentation" shall mean all documentation and methods useful for making and testing AAV Product, which is further described in Exhibit I.

1.12. "Valid Claim" shall mean a claim which has not been withdrawn, cancelled, abandoned, disclaimed or revoked or held unpatentable within (a) an issued/granted and unexpired patent or (b) a pending patent application which has not been pending for more than [**] years from the filing date of the earliest priority application for which the claim receives benefit.

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ARTICLE II - LICENSE GRANT

2.01. St. Jude grants to Licensee:

- (i) a non-exclusive worldwide license to utilize Patent Rights to make, have made on Licensee's behalf, use and sell FIX Product
- (ii) a non-exclusive license to utilize FIX Know-How to make, have made on Licensee's behalf, use and sell AAV Product.

2.02. Licensee shall have the right to sublicense the rights set forth in Section 2.01 to Sub-Licensees through multiple tiers, such sublicenses to be limited to the AAV Product(s) whose commercial rights are being granted to such Sub-Licensees by Licensee and the terms of such sublicenses to be consistent with the terms of this Agreement.

2.03. To facilitate the exercise of rights granted under Section 2.01, St. Jude shall deliver Transfer Documentation to Licensee or its designee through its GMP facility. Upon reasonable, advance request, St. Jude will make personnel from its GMP facility available from time to time to assist in the effective transfer and utilization of FIX Know-How and Patent Rights by Licensee or its designee, provided that Licensee reimburse St. Jude for the full cost of such assistance, including time and overhead for personnel providing assistance, such costs to be agreed in advance with Freeline.

2.04. St. Jude retains the right to utilize Patent Rights and FIX Know-How itself and to offer additional licenses under Patent Rights and FIX Know-How.

ARTICLE III - NONFINANCIAL OBLIGATIONS AND WARRANTIES

3.01. Licensee shall notify St. Jude of the first commercial sale of each AAV Product in writing within thirty (30) days of its occurrence.

3.02. Licensee shall mark all FIX Products with appropriate information with respect to Patent Rights in accordance with the statutes of the United States relating to the marking of patented articles (see 35 U.S.C. §287(a)) if applicable. St. Jude shall inform Licensee of any U.S. patents granted under Patent Rights and the serial number of such patent(s) to assist Licensee in compliance with this marking requirement.

3.03. St. Jude hereby warrants that:

- 3.03.1. it does not own or control any other Intellectual Property or Know-How relevant to the method of manufacturing FIX Product developed by its GMP facility as of the Effective Date.
- 3.03.2. it has the exclusive right, title and interest in and to the Patent Rights and the FIX Know-How, and that it has the full legal right and power to grant the rights and licenses in this Agreement.

ARTICLE IV – FEES AND ROYALTIES

4.01 Licensee agrees to pay to St. Jude an up-front license fee of forty thousand dollars (\$40,000) U.S.; half of which (twenty thousand dollars \$20,000) shall be for the license to Patent Rights due on the Effective Date and payable within thirty (30) days of receipt of invoice from St. Jude, and the other half which (twenty thousand dollars \$20,000)

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shall be for the license to FIX Know-How due upon Licensee's confirmation of complete transfer of the Transfer Documentation and payable within thirty (30) days of receipt of invoice from St. Jude. This license fee payment is nonrefundable and is not creditable against any other payments due to St. Jude under this Agreement.

4.02. Licensee agrees to pay to St. Jude a non-refundable annual maintenance fee of five thousand dollars (\$5,000) U.S. due by March 1 of each year beginning on March 1, 2020 and payable within thirty (30) days of receipt of invoice by Licensee. This annual fee payment may be reduced each year by the amount of any royalty payments made to St. Jude for prior calendar year sales of AAV Product pursuant to Section 4.03 below. For example, the annual payment due March 1, 2020 may be reduced by the amount of any royalty payments made to St. Jude for sales of AAV Product recorded for calendar year 2019.

4.03. Licensee agrees to pay to St. Jude, on a semi-annual basis, the following royalties:

- (i) In exchange for the license to Patent Rights, a royalty of [**] of Net Sales of all FIX Products sold by Licensee, Affiliates or Sub-Licensees. The royalty shall be payable on a country-by-country and product-by-product basis following the first commercial sale of a FIX Product to expiry of the last to expire Valid Claim of Patent Rights; and
- (ii) In exchange for the license to FIX Know-How, a royalty of [**] of Net Sales of all AAV Products sold by Licensee, Affiliates or Sub-Licensees payable on a country-by-country and product-by-product basis for a period, which respect to each such AAV Product, of ten (10) years following the first commercial sale of the AAV Product.

For the avoidance of doubt, royalties are payable once only per unit of FIX Product or AAV Product (as applicable) sold.

4.04 For purposes of calculating the royalty due to St. Jude, Net Sales received in a foreign currency shall be converted into U.S. dollars using the arithmetic average of the daily exchange rate (e.g. GBP/USD) for the calendar half-year (i.e. final day of June or December) using an exchange rate quoted by the Bank of England.

4.05 Royalty Offset. At any time following the approval of a FIX Product by the FDA, St. Jude may submit a written request to Licensee for a reasonable quantity of such FIX Product for noncommercial use. Licensee may accept or deny any such request at its sole discretion. If Licensee accepts such a request and provides FIX Product to St. Jude or its designees, Licensee shall be entitled to reduce its royalty obligation set forth in Section 4.03 by an amount to be agreed upon by the Parties that is intended to approximate the cost incurred by Licensee in providing the FIX Product.

ARTICLE V - PAYMENT AND RECORDS

5.01. Within sixty (60) days of June 30 and December 31 of each calendar year following the first commercial sale by Licensee of an AAV Product, Licensee shall provide St. Jude with a statement setting forth for each of the AAV Products sold by Licensee, Affiliates or Sub-Licensees (without duplication) during the preceding six-month period (from January 1 to June 30 or July 1 to December 31), on a country-by-country basis the Net Sales for each AAV Product for the six month period, a listing of applicable reductions and deductions on an aggregate basis, the total royalty owed for the six month period based on Net Sales of each AAV Product in U.S. dollars, together with exchange rates used for conversion of foreign proceeds, and any credits taken based on prior payment of an annual maintenance fee according to Article 4.02 or royalty offset

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according to Article 4.05 in the same calendar year. If no royalties are due to St. Jude for the period, the report shall so state. Concurrent with this report, Licensee shall remit to St. Jude any payment due for the applicable six month period.

5.02. Licensee shall maintain, and shall cause its Affiliates and Sub-Licensees to maintain, usual books of account and records showing all sales of AAV Product and Net Sales attributable to such sales. Such books and records shall be open to inspection, audit and copying, during usual business hours, by an independent certified public accountant to whom Licensee has no reasonable objection, for two (2) years after the calendar year to which they pertain, for purposes of verifying the accuracy of the royalties paid by Licensee pursuant to this Agreement. Should it be determined by the audit that a discrepancy in the accuracy of royalties paid by Licensee has resulted in a greater than [**] loss of royalty income to St. Jude, Licensee agrees to reimburse St. Jude for its expenses related to performance of the audit, as well as for unpaid royalties to St. Jude, otherwise the costs of the audit shall be paid by St. Jude. Should it be determined by the audit that a discrepancy in the accuracy of royalties paid by Licensee has resulted in an overpayment of royalty income to St. Jude, St. Jude agrees to refund Licensee by the amount of the overpayment.

5.03. All payments due to ST. JUDE under this AGREEMENT shall be forwarded to the following address:

St. Jude Children's Research Hospital
P.O. Box [**]
Memphis, TN 38148-0516

ARTICLE VI - PATENTS

6.01. St. Jude shall have sole responsibility for the drafting, filing, prosecution, and maintenance of all Patent Rights.

6.02. Upon written request by Licensee, St. Jude will provide an annual report of the status of the Patent Rights in all territories in which the Patent Rights exist, and additionally shall promptly notify Licensee of the grant/issuance, withdrawal, lapse, expiry, invalidation or third-party challenge of the Patent Rights in any territory.

ARTICLE VII - CONFIDENTIAL INFORMATION

7.01. The Receiving Party shall (i) maintain any Confidential Information disclosed by the other Party in strict confidence, except that the Receiving Party may disclose or permit the disclosure of any Confidential Information to its Affiliates, directors, officers, employees, consultants, Sub-Licensees (and potential Sub-Licensees) or investors or potential investors and advisors who are obligated to maintain the confidential nature of such Confidential Information and who need to know such Confidential Information for the purposes of this Agreement; (ii) use such Confidential Information solely for the purposes of exercising the rights granted under this Agreement; and (iii) allow its Affiliates, director, officers, employees, consultants, and advisors to reproduce the Confidential Information only to the extent necessary for the purposes of this Agreement, with all such reproductions being considered Confidential Information.

7.02. The obligations of the Receiving party under Article 7.01 above shall not apply to the extent that the Receiving Party can demonstrate that certain Confidential Information (i) was in the public domain prior to the time of its disclosure under this Agreement; (ii) entered the public domain after the time of its disclosure under

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the Agreement through means other than an unauthorized disclosure resulting from an act or omission by the Receiving Party; (iii) was independently developed or discovered by the Receiving Party without use of the Confidential Information; (iv) is or was disclosed to the Receiving Party at any time, whether prior to or after the time of its disclosure under this Agreement, by a third party having no fiduciary relationship with the Disclosing Party and having no obligation to confidentiality with respect to such Confidential Information; or (v) is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, provided that the Disclosing Party receives reasonable prior written notice of such disclosure.

ARTICLE VIII - TERM AND TERMINATION

8.01. Unless terminated earlier,

8.01.1. the payment obligations (fees) due under Article 4.02 for the licenses granted under this Agreement will expire upon the later of (i) the last to expire of Valid Claim of Patent Rights or (ii) the end of the period that is ten (10) years from the first commercial sale of the latest AAV Product, and

8.01.2. the payment obligations (royalties) due under Article 4.03 for the licenses granted under this Agreement will expire as provided in Article 4.03 on a country-by-country and product-by-product basis

and following the end of the applicable royalty term for each AAV Product or FIX Product the license to Factor IX Know-How shall be converted to an irrevocable worldwide non-exclusive royalty-free license.

8.02. Licensee shall have the right to terminate this Agreement, for any reason, upon ninety (90) days prior written notice to St. Jude. Upon such early termination, a final report shall be submitted and any annual fees and/or royalty payments due to St. Jude shall become immediately payable.

8.03. In the event that either party defaults at any time in the performance of any material covenant or condition contained herein, the other party shall have the right to notify the defaulting party of such default and that the notifying party intends to terminate this Agreement unless such default is corrected. Unless correction of such default shall be made within thirty (30) days from the receipt of notice (or further period by agreement of the parties), the notifying party shall be entitled on thirty (30) days notice to the other in writing to terminate this Agreement.

8.04. St. Jude may terminate this agreement immediately upon Licensee's refusal to pay royalties or other fees owed under this Agreement which are due under Articles 4 and 5 and which are undisputed by Licensee.

8.05. St. Jude may terminate this Agreement immediately if Licensee commits any act of bankruptcy, becomes insolvent, files a petition under any bankruptcy of insolvency act or has any such petition filed against it.

8.06. Upon termination of this Agreement,

8.06.1. Licensee shall have the right for [**] to dispose of all AAV Product then on hand, and to complete all orders for such AAV Product then on hand, and (save where Licensee terminates pursuant to Article 8.03) royalties shall be paid to St. Jude with respect to such AAV Product as though this Agreement had not terminated.

8.06.2. Any existing Sub-Licensees as at the date of termination shall have the right to be granted a direct license by St. Jude on equivalent terms as this Agreement.

8.07. Termination of this Agreement shall not terminate Licensee's obligation to pay all royalties which shall have accrued hereunder.

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8.08. Upon early termination of this Agreement for any reason, and subject to Licensee's continuing rights under Article 8.06, Licensee shall cease to utilize Patent Rights and FIX Know-How and shall so certify to St. Jude in writing that Patent Rights are not being used for any purpose by Licensee.

8.09. All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be.

ARTICLE IX – INFRINGEMENT AND VALIDITY

9.01. Licensee shall notify St. Jude of any third party activities which it believes may constitute infringement of Patent Rights or FIX Know-How and any available evidence thereof.

9.02. St. Jude retains the right, but not the obligation, under its own control and solely at its own expense, to prosecute any third party infringement of the Patent Rights or FIX Know-How and to defend the Patent Rights in any declaratory judgment action brought by a third party which alleges invalidity, unenforceability, or non-infringement of the Patent Rights.

ARTICLE X - NOTICES

10.01. Any notice or report required or permitted under this Agreement shall be in writing and shall be sent by hand, recognized national overnight courier, confirmed facsimile transmission, confirmed electronic mail, or registered or certified mail, postage prepaid, return receipt requested to the following addresses:

St. Jude Children's Research Hospital
332 North Lauderdale
Memphis, TN 38105
Attention: [**]
[**]
[**]

Freeline Therapeutics Limited
[**]
215 Euston Road
London, NW1 2BE UK
[**]

ARTICLE XI – RISK ALLOCATION

11.01 Licensee shall, with counsel reasonably acceptable to St. Jude, indemnify, hold harmless, and defend St. Jude, corporate affiliates of St. Jude (including ALSAC, Children's GMP LLC and St. Jude's Graduate School) and their respective Boards of Governors, trustees, officers, inventors, employees and agents (collectively, the "Indemnities"), against any and all claims, demands, suits, losses, damages, costs, fees, and expenses including attorney fees, or other costs arising from or incidental to a [**]

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[**] provided that Licensee shall not be responsible to St. Jude for St. Jude's sole negligence or intentional wrongdoing.

11.02 Other than the warranties made under Section 3.03 above, ST. JUDE MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED.

11.03 In particular, and save as provided in Section 3.03, nothing in this Agreement shall be construed as:

- (a) A warranty or representation by St. Jude as to the validity or scope of any Patent Rights; or
- (b) A warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of any type, including patent infringement, copyright infringement, and trademark infringement; or
- (c) An obligation to bring or prosecute actions or suits against third parties for infringement; or
- (d) Conferring the right to use in advertising, publicity or otherwise the name of the inventors of Patent Rights or the St. Jude name or service mark; or
- (e) Granting by implication, estoppel, or otherwise, any licenses or other rights under any patent of St. Jude that is not covered under Patent Rights.

11.04 Licensee shall provide St. Jude with evidence of insurance coverage sufficient to cover any liability arising from Licensee's indemnification obligations arising under Section 11.01, including but not limited to general comprehensive liability insurance covering each occurrence of bodily injury and property damage in an amount of not less than [**] per claim and [**] annual aggregate, and product liability coverage or other appropriate insurance coverage in the minimum amount of [**] per claim. All such insurance shall be primary and non-contributory. All such insurers shall have a minimum financial rating by A.M Best of A-.

11.05 Licensee shall have sole responsibility for the use and exploitation of the rights granted hereunder, and for any AAV Products manufactured using those rights, including compliance with all applicable safety laws and regulations.

11.06 Neither party shall be liable to the other party for any incidental or consequential damages of any kind arising as a result of breach or any warranty or other term of this Agreement, regardless of whether the party liable or allegedly liable was advised, had reason to know, or in fact knew of the possibility thereof.

ARTICLE XII - MISCELLANEOUS

12.01 The rights and obligations of the parties under this agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to conflict of laws provisions thereof. Any legal action arising from this Agreement shall be brought in New York, New York.

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12.02 If there is a disagreement between the parties on the interpretation of this Agreement or any aspect of its performance, senior representatives of the parties will, within 30 days of receipt of a request from either party to the other, meet in good faith at a mutually agreeable location to seek to resolve the dispute without recourse to legal proceedings. If such good faith discussions fail to resolve the dispute, then either party may commence legal proceedings.

12.03 All matters relating to publication of any data contained in the Transfer Information shall be determined in accordance with the relevant provisions of the JRO ATIMP cGMP Manufacture & Supply Agreement for AAV-MUTC-FLX between Licensee (formerly Newincco 1554), University College London and Children's GMP, LLC effective 16th October 2015.

12.04 This Agreement may not be amended except by an instrument in writing signed by both parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

12.05 Neither St. Jude nor Licensee shall use the name, trademark, service mark, trade name or symbol of the other party or the name of a staff member, employee, student or any affiliated physician or faculty member of the other party, or any adaptation thereof, in any advertising, promotional, or sales literature without the prior written approval of the other party.

12.06 In the event that any provision of this Agreement shall be held invalid or unenforceable for any reason, such invalidity or unenforceability shall not affect any other provision of this Agreement, and the parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent.

12.07 This Agreement shall be binding on the parties hereto and upon their respective heirs, administrators, successors and assigns. This Agreement may not be assigned by Licensee except to a party acquiring substantially all of the assigning party's business to which this Agreement related without the written consent of the other party.

12.08 This Agreement may be executed in separate counterparts, each of which so executed and delivered shall constitute an original, but all such counterparts shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Agreement through duly authorized representatives as of the Effective Date set forth above.

ST. JUDE CHILDREN'S RESEARCH HOSPITAL

LICENSEE (FREELINE THERAPEUTICS LIMITED)

By: [**]

By: [**]

Title: Director, Technology Licensing

Name: [**]
Title: Chief Executive Officer

Date: 04-April-2017

Date: 28 March 2017

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EXHIBIT I
TRANSFER DOCUMENTATION

[**]

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**EXHIBIT II
FIX KNOW-HOW**

[**]

**AMENDMENT #1 TO THE NONEXCLUSIVE LICENSE AGREEMENT
FACTOR IX VECTOR PRODUCTION TECHNOLOGY**

THIS AMENDMENT #1 (“**Amendment**”) is dated February 28, 2020 and is made between:

- 1 **ST. JUDE CHILDREN’S RESEARCH HOSPITAL**, whose principal place of business is at 262 Danny Thomas Place, Memphis, Tennessee 38105, USA (“**St. Jude**”);
- 2 **FREELINE THERAPEUTICS LIMITED.**, a company incorporated under the laws of England and Wales (Company No. 09500073), with its registered office at Stevenage Bioscience Catalyst, Gunnels Wood Road, Stevenage, Herts, England, SG1 2FX United Kingdom (“**Licensee**”);

(The undersigned hereinafter each individually referred to as “**Party**”, and collectively the “**Parties**”)

BACKGROUND

- 1 The Parties are parties to the Nonexclusive License Agreement Factor IX Vector Production Technology dated 24 March 2017 (“**License**”).
- 2 The Parties recognise that clause 4.03 of the License, which deals with the calculation of royalties payable by Licensee, is ambiguous and therefore the intention of clause 4.03 is not clear.
- 3 In order to rectify the issues with clause 4.03 of the License, the Parties now wish to amend the License in accordance with the terms and conditions of this Amendment.

AGREED TERMS

1 AMENDMENTS

- 1.1 With effect from the date of this Amendment, in consideration of the mutual covenants set out in this Amendment and for other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree that the amendments set out in this Amendment shall come into force.

Certain confidential information contained in this document, marked by [], has been omitted because the information (i) is not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.**

1.2 Clause 4.03 of the License shall be deemed deleted in its entirety from the License, and replaced with a new clause 4.03 comprising the following text:

4.03 Licensee agrees to pay to St. Jude, on a semi-annual basis, the following royalties:

- (i) In exchange for the license to Patent Rights, a royalty of [**] of Net Sales of all FIX Products sold by Licensee, Affiliates and Sub-Licensees PROVIDED THAT, but for the license to Patent Rights, such manufacture, use or sale of such FIX Product would infringe a Valid Claim of a Patent Right. The royalty shall be payable on a country-by-country and FIX Product-by-FIX Product basis following the first commercial sale of such FIX Product to expiry of the last to expire Valid Claim of Patent Rights covering such FIX Product; and*
- (ii) In exchange for the license to FIX Know-How, a royalty of [**] of Net Sales of all AAV Products sold by Licensee, Affiliates and Sub-Licensees payable on a country-by-country and product-by-product basis for a period, with respect to each such AAV Product, of [**] following the first commercial sale of the AAV Product.*

*For the avoidance of doubt: (a) royalties are payable once only per unit of FIX Product or AAV Product (as applicable) sold, for example, as a FIX Product is also an AAV Product, in no circumstances shall the [**] FIX Know-How royalty be payable twice in respect of any sale of any single FIX Product that utilises the FIX Know-How; and (b) the Parties recognise that, where the sale of a FIX Product triggers both the [**] Patent Rights royalty defined in clause 4.03(i) above, and the [**] FIX Know-How royalty defined in clause 4.03(ii) above, then both royalties shall be payable.*

1.3 Unless otherwise expressly stated herein, all terms defined in the License shall have the same meaning in this Amendment.

1.4 This Amendment, together with the License, constitute the entire agreement between the Parties with respect to the subject matter hereof and shall supersede all previous representations, agreements and other communications between the Parties, both oral and written.

1.5 Save as expressly set out in this Amendment, the terms of the License (as amended) shall remain in full force and effect. In the event of any inconsistency between the terms of this Amendment and the License, the terms of this Amendment shall prevail.

1.6 No variation of this Amendment shall be valid unless it is in writing and signed by or on behalf of each of the parties.

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1.7 The rights and obligations of the parties under this Amendment shall be governed by and construed in accordance with the laws of the State of New York, without regard to conflict of laws provisions thereof. Any legal action arising from this Amendment shall be brought in New York, New York.

IN WITNESS WHEREOF this Amendment has been signed by the duly authorised representatives of the Parties.

Signed for and on behalf of **ST. JUDE CHILDREN'S RESEARCH HOSPITAL**

Signature [**]

Name (Printed) [**]

Title: Director, Office of Technology Licensing

Signed for and on behalf of **FREELINE THERAPEUTICS LIMITED**

Signature [**]

Name (Printed) [**]

Title: SVP Strategy